

Appendix A:

Corporate Positions and Persons Holding Them
Based on BPV/C. R. Bard Organization Charts

**Corporate Positions and Persons Holding Them
Based on BPV/C. R. Bard Organization Charts**

<u>Position/Title</u>	<u>Name</u>	<u>Years</u>	<u>Deposed?</u>
President BPV	J. McDermott	2003-2006	Pre-MDL
	J. Beasley	2007-2012	
	S. Williamson	2013-present	MDL
VP Research & Development	L. DeCant	2003-2006	MDL
	A. Raji Kubba	2007-2011	MDL
	S. Randall (Program Director)	2012	
	K. Boyle	2013-present	
VP Marketing	K. Shifrin	2003-2006	MDL
	B. Little	2007-2011	MDL
	J. LeMaster	2014-present	
VP Sales	J. DeJohn	2003-2007	MDL
	B. Doherty	2008-2012	MDL
	P. O'Brien	2013-present	
VP Quality	D. Uelman	2003-2004	Pre-MDL
	G. Schulz	2006-2010	Pre-MDL
	C. Modra	2011-2014	Pre-MDL
	G. Conrad	2015-present	
VP Regulatory/Clinical	M. Edwards	2003-2005	Pre-MDL/ MDL
	S. Allen	2006	Pre-MDL
	J. Van Vleet	2007-present	MDL
Primary IVC Filter Engineers/Program Managers	R. Carr	2003-2009	Pre-MDL
	A. Tessmer	2003-2004	Pre-MDL
	A. Mukherjee	2004-2005	Pre-MDL
	A. Chanduskzo	2006-present	Pre-MDL
	M. Casanova (Program Director)	2010-2011	
	M. Randall	2009-present	
IVC Filter Product Manager	J. Hudnall	2003-2007	Pre-MDL

	B. Enlow	2007	
	B. Baird	2008-2009	MDL
	K. Romney	2001-present	
National Training Manager/ Professional Development	D. Rauch	2003	
	M. Kunning	2004-2008	
	M. Wilson	2008-2010	
	M. Perko	2011	
	D. King	2012	
	R. Shreiner	2013	
	L. Gleason	2014-present	
BPV Regional Sales Managers	R. Cortelezzi	2004-2007	
	R. DeLeon	2004-2007	MDL
	J. Sullivan	2006-2011	MDL
	D. Orms	2008-2012	MDL
	H. Yentz	2010-2012	
	T. Hug	2012-2013	
	M. Curtis	2013	
	R. Curry	2013, 2016	
	E. Macaluso	2014	
	T. Dieckhoner	2015	
CR Bard SVP Quality & Regulatory Affairs	G. Dolch (Sr. VP)	2008-2013	
	P. Christian	2014-present	
CR Bard VP Regulatory Science/Affairs	C. Ganser	2005-2006	Pre-MDL/ MDL
	J. Howard	2007	
	P. Christian	2008-2010	
	A. Casper	2011-present	
CR Bard VP Clinical Affairs	B. Barry	2005	Pre-MDL
CR Bard VP Quality	C. Ganser	2007-2010	(See above)
	P. Christian	2011-2013	
	G. Schultz	2014-present	(See above)
CR Bard SVP Science, Technology & Clinical Affairs	J. DeFord	2005-present	MDL

Medical Director/ VP Clinical Affairs	Dr. J. Lehmann	2003-2004	Pre-MDL
	Dr. D. Ciavarella	2006-present	Pre-MDL
	Dr. G. Altonoga	2010-	Pre-MDL

Appendix B:

**Examples of Unresponsive Answers, Bard's Direct Examination, and State/Federal
Coordination Issues**

Examples of Unresponsive Answers, Bard's Direct Examination, and State/Federal Coordination Issues

William R. Little, 7/27/2016

Page/Line	Little depo text
64:16-65:1	<p>Q. Do you agree that a company like Bard should not put profits for the sales of its IVC filters over patient safety?</p> <p>A. I do agree with that.</p> <p>Q. All right.</p> <p>A. Patient safety is paramount to what we do and they go hand in hand. And if you make devices that aren't safe, profits ultimately go away. And the way for us to be successful was to focus on continuous improvement, put the patient area of expertise.</p>
67:12-68:7	<p>Q. All right. We talked about adverse events earlier. Do you agree that Bard should never under-report the adverse events in their complaint files that are associated with IVC filters?</p> <p>A. Yeah, I agree with that. We should -- as we learn about them, you know, FDA mandates that and it's the right thing to do and we should do the best we can.</p> <p>Q. Setting aside the FDA, why is it important not to under-report?</p> <p>A. Well, it's hard to set aside the FDA. I mean, that's -- you know, we're trying to get the right information to our clinicians so that they can make good decisions about risks and benefits of devices, and the system is imperfect and we take what we have. And I can tell you at Bard, we took a really conservative approach to reporting adverse events because it was the culture and it was the right thing to do.</p>
94:21-95:13	<p>Q. With respect to the comment that "we -- referring to Bard -- "knew very little about the long-term clinical performance of this device when we launched it," was that your understanding that Bard knew very little about the long-term clinical performance of the Recovery filter when they launched it?</p> <p>[Bard's attorney]: Object to the form and foundation. You can respond.</p> <p>A. So I wasn't there in 2004, so I don't know. But I can tell you, it's impossible to know long-term performance about anything without long-term data. And by definition, any product that gets launched at any time doesn't have long-term data. So I think that's true. It's also obvious by the definition of any product for any category that's ever been launched ever.</p>

Page/Line	Little depo text
96:14-97:11	<p>Q. With respect to the Eclipse filter, when you were with Bard, are you aware of any prospective long-term clinical trial designed to assess the safety of that filter?</p> <p>A. I'm not aware of that.</p> <p>Q. All right. What is a prospective clinical trial?</p> <p>A. It's a study that's forward-looking. So you start with a question, a hypothesis, and then you study it moving forward and then see what the results are.</p> <p>Q. Now, do you acknowledge that that is a way for a company like Bard to develop a long-term understanding of the clinical performance of a device such as an IVC filter?</p> <p>A. It's a way. There could be other ways too. I mean, bench testing is something we use frequently. And we tend to follow FDA guidance around the requirements for labeling. And working in concert with FDA and our clinician partners tends to be the best way to do things. There's a lot of ways, some are better than others.</p>
101:5-21	<p>Q. Do you know what Bard knew about the long-term clinical performance of the G2 filter?</p> <p>A. Well, I suspect that long-term is still going on now, right? There are patients that have G2 filters today that are doing great that have likely had pulmonary embolisms prevented because they have that filter in place. So it's essentially impossible to get a complete look at all the information. What we try to do is get appropriate meaningful information in a fair and balanced way looking at it, with good perspective about all these devices. And we do that through reporting. We work with FDA. There's a lot of ways that we get after that. So it's a complex question that doesn't deserve a simple answer.</p>
102:15-103:18	<p>Q. Okay. So what you're saying is that Bard's understanding of the long-term clinical performance of the G2 filter during your employment there would have related to bench testing and adverse event reports?</p> <p>A. That would be part of it.</p> <p>Q. All right.</p> <p>A. I think there would be additional things beyond that: If we had complaint reports, if we had our own clinical information that may have come from clinicians. There's a lot of ways that we learn about this, none of which can be taken in isolation. And we do the best we can to understand how devices perform knowing that none of them is perfect and that we want to try to make continuous improvement as we learn about things that we can make these devices better.</p> <p>Q. And just so I understand your answer --</p>

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	<p>A. Hold on. I'm not done.</p> <p>Q. Okay.</p> <p>A. It's important to keep in mind that these are lifesaving devices and none of these devices is perfect. And even a device that's functioning as intended can still result in bad outcomes. So we have to take that all into -- into consideration when we're thinking about the performance of these devices. And that's exactly what we tried to do.</p>
106:12-111:25	<p>Q. Sure. Was there any human clinical testing of the G2 filter, the G2 Express filter, or the G2 -- I'm sorry -- or the Eclipse filter that you're aware of?</p> <p>A. Not that I'm aware of.</p> <p>Q. All right.</p> <p>A. I don't know. It's possible that there was. I don't know. Sometimes FDA requires a 510(k) --</p> <p>[Plaintiffs' attorney R. Lopez]: Sir, the answer is you don't know.</p> <p>[Bard's attorney]: Hold on. Ramon, hold on. No, you're not going to sit here and talk to the witness that way.</p> <p>[Plaintiffs' attorney R. Lopez]: Jim, can I just say something?</p> <p>[Bard's attorney]: No.</p> <p>[Plaintiffs' attorney R. Lopez]: We have a limited amount of time -- I'm talking to you.</p> <p>[Bard's attorney]: No. You're interrupting the witness in the middle of an answer. Okay? Let him finish his answer. And then, Ramon, if you've got something to say, you can say it.</p> <p>[Plaintiffs' attorney R. Lopez]: Okay. I'll let him finish and then we have to talk.</p> <p>[Bard's attorney]: All right. Okay.</p> <p>[Witness]A. I think it's important to keep in mind that depending on the FDA requirements, sometimes FDA under a 510(k), which I'm sure you're familiar with, will require a clinical in advance, sometimes they'll require it after clearance of the device. And to answer, I don't know what the FDA requirement was on that filter, if it was a 510(k) with a clinical before or after, so I don't know the answer, but it could go either way and that's why I think it's important to have the context.</p> <p>[Plaintiffs' attorney R. Lopez]: Okay. I'd like to say something. The question was simply, was there any human clinical testing of the G2 filter, the G2 Express or the G2 -- I'm sorry -- or the Eclipse filter that you're</p>

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	<p>aware of? He answered "Not that I'm aware of." And then he went on and gave a speech about something.</p> <p>[Bard's attorney]: All right. And he's got a perfect right to explain his answer.</p> <p>[Plaintiffs' attorney R. Lopez]: No, he doesn't.</p> <p>[Bard's attorney]: Yes, he does.</p> <p>[Plaintiffs' attorney R. Lopez]: That's not explaining his answer. Jim, Jim --</p> <p>[Bard's attorney]: Hold on. First of all, Joe is asking the questions right now. You'll get your chance.</p> <p>[Plaintiffs' attorney R. Lopez]: I don't care. This is my deposition too and I --</p> <p>[Bard's attorney]: That's fine.</p> <p>[Plaintiffs' attorney R. Lopez]: This is as much my time --</p> <p>[Bard's attorney]: I mean, what are you going to do? Just tell the witness what he can do and what he can't do?</p> <p>[Plaintiffs' attorney R. Lopez]: No, but I was hoping you were going to -- you would do that.</p> <p>[Bard's attorney]: I mean, the witness is here. He can answer questions to the best of his ability and that's what he's doing.</p> <p>[Plaintiffs' attorney R. Lopez]: Okay, Jim, I'm not done. Okay. You're interrupting.</p> <p>[Bard's attorney]: Okay. Go ahead.</p> <p>[Plaintiffs' attorney R. Lopez]: And this is -- again, don't take this personal. I'm just trying to have this process go smoothly. And according to the rules, the rules say that if you ask a question you're supposed to give an answer. He gave a perfectly appropriate answer, "Not that I'm aware." That's all the question asked for.</p> <p>[Bard's attorney]: Right.</p> <p>[Plaintiffs' attorney R. Lopez]: And then we went on for, you know, paragraph after paragraph about stuff that wasn't asked. And I think it's your obligation, that's why I'm talking to you, to instruct the witness. And you probably instructed him to say whatever he wanted to say no matter what the question was. And I think that's wrong. I just want to be on the record about that if we have to go and deal with the Judge on this.</p> <p>[Bard's attorney]: That's totally fine. Totally fine.</p> <p>[Plaintiffs' attorney R. Lopez]: Okay. I'm not done. I'm asking you as a lawyer who knows the rules to properly instruct the witness who I think probably doesn't know that he's not supposed to go beyond the scope of the</p>

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	<p>question, but I have a feeling that you may have told him he can and should.</p> <p>THE WITNESS: Sir, I can tell you, look, what he told me --</p> <p>[Plaintiffs' attorney R. Lopez]: I'm sorry, sir.</p> <p>THE WITNESS: I understand, but I want to speak.</p> <p>[Bard's attorney]: Are you still talking, Ramon, or are you done?</p> <p>THE WITNESS: I'm going to speak. He told me to answer the questions honestly, and that's what I'm trying to do. And there's context to what we're trying to do. I'm trying to give you the right information.</p> <p>[Plaintiffs' attorney R. Lopez]: All right. Well, he's talking to me. He has an opportunity when we're done if there's any clarification --</p> <p>[Bard's attorney]: He understands that.</p> <p>[Plaintiffs' attorney R. Lopez]: -- if there's anything that he wants to ask you to clarify, that's his opportunity to do that. He can do that if he wants to. Even if we have to come back tomorrow, he can do that. So I'm just saying this because of the limited amount of time, we're asking very specific questions. And the rules are to just answer the question that's been asked. There's a rule against going beyond the scope and giving responses that are nonresponsive. That's why we keep making these motions to strike. Again, I'm not trying to lecture you. I'm just frustrated because, you know, the first hour and a half of this deposition, I mean, there's been almost every reason for us to make motions to strike beyond the scope of the question.</p>
134:12-135:19	<p>Q. What if this filter migrates all the way up to the heart --</p> <p>A. Yes.</p> <p>Q. -- would you have any patient safety concerns in that circumstance?</p> <p>[Bard's attorney]: Yeah, I was just letting him try and finish the question.</p> <p>THE WITNESS: Okay.</p> <p>A. You could, yeah. I mean, if you had a device that ended up, let's say, in the right atrium or in the right ventricle, you could have a situation where that patient might have to go to surgery. And any time you're exposing a patient to surgery, that would be an adverse event that we would report and that we would, you know, try to mitigate with future designs or -- and sometimes you can have filters that even the best designed filter -- you get a big clot that comes in there and those filters can just move and they can migrate up into the heart. And the filter can be doing exactly what it's supposed to do, but the clot burden is so big that it could move that filter. So, again, it's not a simple answer. And the filter may be doing exactly what it's supposed to do, but you still have an adverse event. And if that filter weren't there, then you have this massive clot that's going either into the</p>

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	lungs or causing cardiac arrest. So, again, they don't stop everything, but that's what they're designed to do.
159:1-160:13	<p>Q. So a patient that doesn't need a permanent filter, that only needs a temporary filter --</p> <p>A. Mm-hmm (affirmative).</p> <p>Q. -- what this says is, We can take it out at any time?</p> <p>A. That's certainly --</p> <p>Q. That's not true, is it?</p> <p>A. That's certainly what they're designed to do. Now, sometimes devices don't perform as they're designed, and that happens with all devices. And it certainly can happen with filters and other -- you know, we call those "adverse events," and we try avoid those. But they absolutely happen, and I'm not trying by any way to say that these devices are perfect and that they don't ever have complications, just to be clear.</p> <p>Q. But, sir --</p> <p>A. That's why the warning label. And all these things happen.</p> <p>Q. Recognizing that it's important to get the truth out there --</p> <p>A. Mm-hmm (affirmative).</p> <p>Q. -- this doesn't tell the patient that you may be saddled with a permanent filter even though you only need a temporary filter?</p> <p>A. Yeah, if this were the only document the patient got and they never had a discussion with the clinician and they never had any other access, then this would not be complete.</p> <p>Q. All right. A We would need broader information. Certainly a clinician, you know, as part of their discussions with patients would absolutely be required to discuss the risks and benefits of any procedure. And this is one important part, but this is not in isolation the complete story for a patient.</p>
208:16-209:20	<p>Q. The next sentence: "The change in brand name and codes was to create a break with the baggage associated with the previous versions despite the fact that the new iteration was the same as G2X in every way but one." Did I read that correctly?</p> <p>A. Mm-hmm (affirmative).</p> <p>Q. Yes?</p> <p>A. Yes.</p> <p>Q. All right. And it doesn't tell us what the baggage is that that is referring to, does it?</p> <p>A. No.</p>

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	<p>Q. All right. And what they're saying is, We're going to change the name of this filter and we're going to disassociate ourselves with the baggage even though it's the same filter other than the fact that it's been electropolished?</p> <p>A. Well, and as we talked about before, that baggage, I think a lot of that was unjust, unfair baggage. I mean, if we looked at what came with filter law and what came with our competitors out there, so having something that could potentially improve upon any kind of fracture rates is a good thing. And we make naming decisions all the time. And whoever wrote this -- I'm not sure who it was, but it's probably one of the marketing guys in Filters -- that may have been his or her impression at the time. And I don't doubt that that's what they were thinking.</p>
226:16-227:5	<p>Q. What he says is we could be our own enemy by creating products or processes that are not robust and of high quality.</p> <p>A. Right. It would be very different if he said we are our own enemies because we're doing this. That's not what he's saying. He's saying we could be if we did this. And it's a reinforcement of we have to produce things that are robust and high quality. I mean, that is, obviously, his intent here. And to characterize it otherwise is just -- that's a misrepresentation. This exactly reinforces what I'm saying is that we're trying to do the right thing, build things that are robust and high quality.</p>
229:18-230:19	<p>Q. All right. So she's identifying that as an enemy of Bard?</p> <p>A. Yes. We're trying to get rid of complications. They're bad. We could talk about this all day. I mean, this to me is -- this is -- so reinforces the culture of we've got this cross-functional team that's out here taking an honest assessment of ourselves, saying, "Hey, we have to make sure we don't have processes that get in the way. We've got to build robust products. We have to develop evidence. We have to do all these right things. There is a culture of do the right thing here. And this is a pretty good document that says that. And, you know, what's so interesting, when I look at the bottom one, which isn't highlighted --</p> <p>Q. We're not there yet. We'll get to it.</p> <p>A. -- but I think it's important that, you know, they talk about lawyers and legal advertisements, that they put fear in our current customers. And that was absolutely true. They were creating this fear out there that was resulting in bad things. And so here's a team trying to do the right thing. We can spend all day on this.</p>
230:24-231:21	<p>Q. We're referring to Ms. Creal's comments. She identifies a lack of prospective data showing the effectiveness of filters.</p> <p>A. Yes.</p> <p>Q. This is in 2010?</p>

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	<p>A. Mm-hmm (affirmative).</p> <p>Q. A lack of prospective data indicating that these filters are effective?</p> <p>A. Mm-hmm (affirmative).</p> <p>Q. Was that information, to your knowledge, ever provided to the medical community?</p> <p>A. I think that the information that was out there was very clear. There was not a doubt in the mind of clinicians about what clinical data on filters is available. I mean, there's Society guidelines. So would we love to have a prospective randomized controlled trial? Yeah. They're really expensive. They're hard to run. The FDA and industry and clinicians never got a way to get that done. And would we love to have it, yes. Love to have it. We don't. It's imperfect.</p>
232:15-233:1	<p>Q. Well, let me back up. Are you telling us that during the time you were at Bard, you were with Bard, you're not aware of any efforts by Bard to fund or perform a prospective study to assess the effectiveness of its filters?</p> <p>A. So you have to keep it in context of everything else we were doing. We didn't do them on stents or balloons or wires. And were they required, we would absolutely do them. That wasn't the requirement. Would we like to have it? Absolutely, yes.</p>
432:1-442:3 [Bard Direct Examination]	<p>1 [Bard Attorney]:</p> <p>2 Q Okay. Mr. Little, let me follow up a little bit</p> <p>3 about your testimony that you gave about your</p> <p>4 work life while you were at C.R. Bard.</p> <p>5 And you've described yourself several times</p> <p>6 as a marketing guy.</p> <p>7 A Yeah.</p> <p>8 Q Is that right?</p> <p>9 A That's right.</p> <p>10 Q And so would you describe for the jury the</p> <p>11 interrelationship between the department that</p> <p>12 you worked in and the other departments within</p> <p>13 C.R. Bard?</p> <p>14 A Sure. So I managed the marketing team, and we</p> <p>15 had multiple functions at Bard. So you had the</p> <p>16 quality group, the regulatory group, human</p> <p>17 resources, sales, operations, finance. And</p> <p>18 within marketing, I worked with the commercial</p> <p>19 team, the sales folks, the product managers; and</p> <p>20 I also served on the management board, which was</p> <p>21 made up of the functional heads of all those</p> <p>22 functions that I listed earlier.</p> <p>23 Q Now, in your capacity as the vice president of</p>

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24	marketing, were you responsible for working with
25	and communicating with the FDA?
	433
1	A No.
2	Q Were there other folks at Bard that had those
3	job functions?
4	A Yes.
5	Q And in your capacity as the vice president of
6	marketing, were you in charge of the research
7	and development of new products?
8	A No.
9	Q Were there other folks at Bard who were in
10	charge of those functions?
11	A Yeah. R&D was in charge. And we contributed,
12	and we helped and, you know, provided inputs,
13	but R&D was in charge of that.
14	Q Was there also a clinical department at Bard?
15	A Yes.
16	Q And were you in charge of that department?
17	A No.
18	Q And so were there other folks that were
19	responsible for that function?
20	A That's right.
21	Q And what types of things would those people do?
22	A So they would run clinical trials -- the
23	clinical specifically?
24	Q Yes.
25	A If there were clinical trials, they certainly
	434
1	would run that. There was also a medical
2	affairs component in there where if there were
3	times where we maybe needed to have
4	clinician-to-clinician discussions, the medical
5	affairs folks would take part in those.
6	Q And would the same be true for tracking and
7	monitoring adverse events? Were there people at
8	Bard that did that?
9	A There's a huge department.
10	Q And what was that department known as?
11	A So quality assurance, QA.
12	Q And that was not your function?
13	A No.
14	Q But did you interact with all those departments
15	from time to time?
16	A Yes.

Page/Line	Little depo text
	<p>17 Q And did you have some understanding of how all</p> <p>18 those departments functioned?</p> <p>19 A Generally, yes, and it was my job to be aware,</p> <p>20 but not necessarily to be the decider on</p> <p>21 functional activities that were outside of my</p> <p>22 scope.</p> <p>23 Q Mr. Little, when did you start at Bard? Do you</p> <p>24 remember roughly when that was?</p> <p>25 A Yeah. It was about November of '08.</p> <p style="text-align: center;">435</p> <p>1 Q And I think you mentioned multiple times during</p> <p>2 your prior examination by plaintiff's counsel</p> <p>3 that by the time you got there, the Recovery</p> <p>4 filter was not being sold; is that right?</p> <p>5 A That's right.</p> <p>6 Q And so did you ever work on the Recovery filter?</p> <p>7 A I did not.</p> <p>8 Q And you mentioned a couple of times in your</p> <p>9 deposition that you thought the Recovery filter</p> <p>10 may have been recalled.</p> <p>11 A Yes.</p> <p>12 Q Do you remember that?</p> <p>13 A I do.</p> <p>14 Q And do you have any specific understanding that</p> <p>15 that's the case, or is that just a general</p> <p>16 recollection?</p> <p>17 A It's general. I'd still love to know the</p> <p>18 answer.</p> <p>19 Q Okay. So you don't really know one way or the</p> <p>20 other if that product was ever recalled?</p> <p>21 A That's right.</p> <p>22 Q Mr. Little, you were asked some questions about</p> <p>23 off-label marketing.</p> <p>24 Do you remember that?</p> <p>25 A Mm-hmm (affirmative).</p> <p style="text-align: center;">436</p> <p>1 Q And would you tell us again -- remind the</p> <p>2 jury -- what Bard's policies were in regard to</p> <p>3 off-label marketing?</p> <p>4 A Yeah. And it's not just Bard. It's FDA, too.</p> <p>5 It's very clear. You know, we always talk about</p> <p>6 the first rule of the FDA: "Thou shall not</p> <p>7 promote off-label." And we take it seriously.</p> <p>8 It's something that is strictly prohibited. And</p> <p>9 it's not to say that -- you know, we along with</p>

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	<p>10 any other device company out there -- you have</p> <p>11 the occasional rogue rep that may do something,</p> <p>12 and we do everything we can to train them and to</p> <p>13 have policies and procedures and training to</p> <p>14 make sure that it doesn't happen.</p> <p>15 When it inevitably does on occasion, you</p> <p>16 know, we'll then try to follow up with those</p> <p>17 folks, make sure that they understand the rules,</p> <p>18 that they're reprimanded, and it doesn't happen</p> <p>19 again. And it's a constant battle that we face</p> <p>20 out there.</p> <p>21 [Plaintiffs' Attorney]: Just note my</p> <p>22 objection and motion to strike any</p> <p>23 reference to the "FDA."</p> <p>24 [Bard Attorney]:</p> <p>25 Q Mr. Little, I'm going to put up on the screen a</p> <p>437</p> <p>1 document that was used prior in your deposition,</p> <p>2 and I believe it was marked as Exhibit 2000.</p> <p>3 A Okay.</p> <p>4 Q Do you remember answering some questions about</p> <p>5 this document?</p> <p>6 A I do.</p> <p>7 Q And did you know who Stacy Taiber is? Do you</p> <p>8 know who that individual is?</p> <p>9 A I don't know who that is.</p> <p>10 Q And do you know the addressee? Is that Brent</p> <p>11 Adamson, MD? Do you know that individual?</p> <p>12 A I don't.</p> <p>13 Q You were asked some questions about this</p> <p>14 document and whether or not it would have been</p> <p>15 an appropriate marketing function for Bard to</p> <p>16 pursue this.</p> <p>17 A Yeah.</p> <p>18 Q Because there is a mention of prophylactic use</p> <p>19 of an IVC filter.</p> <p>20 A Right.</p> <p>21 Q Right?</p> <p>22 And would that be okay with Bard?</p> <p>23 A No.</p> <p>24 Q Let's look specifically --</p> <p>25 [Plaintiffs' Attorney]: Object as to form.</p> <p>438</p> <p>1 [Bard Attorney]:</p> <p>2 Q -- up at the top where it says, "(AUTO DATE)"?</p>

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	<p>3 Do you see that?</p> <p>4 A I do.</p> <p>5 Q And do you know generally what that might be?</p> <p>6 [Plaintiffs' Attorney]: Form.</p> <p>7 A I'm guessing that this was some sort of mail</p> <p>8 merge thing where it would populate whatever</p> <p>9 date it was with the letter, but it looks like</p> <p>10 there's no date on there. So I don't know</p> <p>11 that -- first of all, I don't know Stacy. I</p> <p>12 wasn't there when Recovery came out, and I don't</p> <p>13 know that this thing ever went out. So there's</p> <p>14 a lot of "I don't know here" on here.</p> <p>15 [Plaintiffs' Attorney]: Move as to strike</p> <p>16 everything after "I'm guessing."</p> <p>17 [Bard Attorney]:</p> <p>18 Q Would it have been the typical practice at Bard</p> <p>19 to send out a letter that had "(AUTO DATE)" on</p> <p>20 it?</p> <p>21 [Plaintiffs' Attorney]: Form. Predicate.</p> <p>22 [Bard Attorney]:</p> <p>23 Q You can respond.</p> <p>24 A We would not have done something like that. We</p> <p>25 certainly wouldn't have directed something like</p> <p style="text-align: center;">439</p> <p>1 that from the organization.</p> <p>2 Q Mr. Little, you've already said you have no idea</p> <p>3 whether this letter was ever mailed or not.</p> <p>4 A I have no idea, but just seeing the auto date,</p> <p>5 that would be unusual to think that somebody</p> <p>6 would mail that out with that in there.</p> <p>7 Q Right.</p> <p>8 And do you recall being asked --</p> <p>9 [Plaintiffs' Attorney]: Motion to strike.</p> <p>10 [Bard Attorney]:</p> <p>11 Q -- several questions by plaintiff's counsel</p> <p>12 about whether Bard did anything to correct this</p> <p>13 letter and they followed up with this doctor?</p> <p>14 Do you remember that?</p> <p>15 A I recall being asked about it.</p> <p>16 Q And if this letter was never sent, was never</p> <p>17 mailed, what would Bard's obligation be to</p> <p>18 follow up?</p> <p>19 [Plaintiffs' Attorney]: Objection. Form.</p> <p>20 [Plaintiffs' Attorney]: Form.</p> <p>21 A They wouldn't follow up with the doctor because</p>

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	<p>22 the doctor never would have gotten the letter,</p> <p>23 so there wouldn't be an obligation.</p> <p>24 [Bard Attorney]:</p> <p>25 Q All right. Thank you.</p> <p style="text-align: center;">440</p> <p>1 Let me ask you some questions now about the</p> <p>2 documents that you were shown that had some</p> <p>3 financial predictions, prediction of sales, and</p> <p>4 things like that.</p> <p>5 A Yeah.</p> <p>6 Q Do you recall being shown those documents?</p> <p>7 A I do.</p> <p>8 Q And are those types of documents, are they</p> <p>9 necessary for Bard's functioning from a business</p> <p>10 perspective?</p> <p>11 A Yeah. We forecast. I mean, that's core to what</p> <p>12 the marketing folks do.</p> <p>13 Q And silly question, but Bard is a business,</p> <p>14 right?</p> <p>15 A We are. We are a publicly-traded company.</p> <p>16 Q And does it have shareholders?</p> <p>17 A Yes.</p> <p>18 Q Does it have a responsibility to its</p> <p>19 shareholders?</p> <p>20 A Yes.</p> <p>21 Q Is one inherent goal in a business to try and</p> <p>22 turn a profit?</p> <p>23 A Yes.</p> <p>24 [Plaintiffs' Attorney]: Form.</p> <p>25 [Bard Attorney]:</p> <p style="text-align: center;">441</p> <p>1 Q And is part of turning a profit continuing to</p> <p>2 make developments with products and continuing</p> <p>3 to develop new products?</p> <p>4 A Yes.</p> <p>5 Q And is it important for a business like Bard</p> <p>6 that is selling medical devices to have sound</p> <p>7 relationships with doctors?</p> <p>8 A Yes.</p> <p>9 Q And is that something that is important from a</p> <p>10 long-term perspective?</p> <p>11 A It's critical from a long-term perspective.</p> <p>12 Q Can you explain that?</p> <p>13 A Yeah. So, you know, Bard's a company that's</p> <p>14 been around for over a hundred years, and we</p>

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	<p>15 think about the business over the long run. And</p> <p>16 making sound decisions, good investments, being</p> <p>17 thoughtful about how we communicate to patients,</p> <p>18 to investors, to the FDA, all of that goes into</p> <p>19 being a company that's successful over a</p> <p>20 century. And we were serious about that.</p> <p>21 It wasn't about, you know, this quarter,</p> <p>22 this sale, this product. It was about long term</p> <p>23 doing the right thing and building the value of</p> <p>24 the company, and I think we did that. We</p> <p>25 continue to do that. You know, I haven't been</p> <p style="text-align: center;">442</p> <p>1 there for five years, but they continue to do</p> <p>2 that in my absence.</p> <p>3 [Plaintiffs' Attorney]: Form.</p>

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165:20-169:19	<p>Q. But if that is what it says, is that something you would have wanted to know?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. I'd rather not answer that question unless I knew. I don't like to answer hypotheticals in a deposition probably.</p> <p>Q. I know, but I can ask you a hypothetical. If that is what it says, would you have wanted to know?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. I think I -- I've answered it as best I can.</p> <p>Q. If that is what it says -- you haven't answered it at all. If that is what it says, is that information you would have wanted to know?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. I can't answer that question. I don't know what it says. So you can continue to ask me in different ways, but I don't know what the flow of events were, what the data they collected were. It's just -- and I'm not trying to be difficult. You're trying to get me to say something that I don't for a fact know, and I'm just -- I'm not comfortable saying that.</p> <p>Q. Yeah. I mean, I --let me ask it as simply as I can.</p> <p>A. Okay.</p> <p>Q. If that document says that Bard internally found an increased risk of death, filter-related death --</p> <p>A. Um-hum.</p> <p>Q. -- with the Recovery filter versus the Simon Nitinol and other filters, is that something you would have wanted to know about?</p> <p>[Bard's attorney]: Object to the form. Asked and answered, I think four times now.</p> <p>A. Maybe I'll answer it this way. If that's what it said, then the Bard that I worked for would not have sold the filter.</p> <p>Q. Okay. Let me try again. Same question. If that's what it said, would you have wanted to know -- this isn't a trick question -- would you personally have wanted to know about it?</p> <p>[Bard's attorney]: Dave, he's -- I'm going to object to the form. This is harassing. It's argumentative.</p> <p>[Plaintiffs' attorney]: Harassing. Stop it. If you want to -- if you want to instruct him not to answer, do it. Otherwise object to form.</p>

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	<p>[Bard's attorney]: Okay. Let's all be professional and respectful of each other.</p> <p>[Plaintiffs' attorney]: I'm going to get -- we're going to answer this question.</p> <p>[Bard's attorney]: He's answered it five or six times.</p> <p>[Plaintiffs' attorney]: You haven't answered it once.</p> <p>Q. The question is, again: If this -- if that document says that Bard internally did an analysis and found an increased risk of death with the Recovery filter versus the SNF and other filters, is that something you would have wanted to know about?</p> <p>[Bard's attorney]: Object to the form. Asked and answered.</p> <p>A. And I can't answer that question because I don't believe that's what they found.</p> <p>Q. My question is a hypothetical, sir. Answer the question I'm asking, not the question you want to.</p> <p>A. I would -- as a sales rep in the field, I would want to know the devices I was representing were safe and effective. And I trusted in Bard and the people that are on this email to know whether that was true.</p> <p>Q. Okay. And would you consider a device safe if it had an increased risk of death over competitors and its predicate?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. If a device has an increased risk of death, I would want to understand why.</p> <p>Q. Would you want to know that it had an increased risk?</p> <p>A. I would want to understand how we came to that conclusion.</p> <p>Q. Would you want to know if it had an increased risk?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. I would want to know how we arrived at that.</p> <p>Q. This is -- that's not my question. My question isn't do you -- would you want to know how they arrived at it. My question is: Would you want to know if there was an increased risk of death with your product?</p> <p>A. Well, sure.</p>
202:20-204:16	<p>Q. Assuming this information is accurate, is this something that would be important to you to know?</p>

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	<p>A. If that -- yes. For sure. But it's hard to comment on that. Those incidents appear to be higher than our own incidents. And the Tulips -- it's just -- it's just hard to know if that's accurate, honestly; right?</p> <p>[Plaintiffs' attorney]: I'm -- move to strike the remaining portion as nonresponsive.</p> <p>Q. My question is: Assuming this is accurate, is this something you would have wanted to know about?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. Assuming it's accurate, we would have known.</p> <p>[Plaintiffs' attorney]: Move to strike as nonresponsive.</p> <p>Q. The question is: Assuming this is accurate, is this something you would have wanted to know about?</p> <p>[Bard's attorney]: Object to the form.</p> <p>A. Assuming this is accurate, we wouldn't need to get it in an email from someone. We would have known.</p> <p>[Plaintiffs' attorney]: Again, move to strike as nonresponsive.</p> <p>Q. My question is really, really simple.</p> <p>A. I disagree.</p> <p>Q. Assuming this information is accurate, is this something you would have thought was important?</p> <p>[Bard's attorney]: Object to the form. Asked and answered. Argumentative.</p> <p>A. I believe that if this information is accurate, Bard knew. And I didn't necessarily need to know. They knew. Whoever needed to know knew it.</p> <p>[Plaintiffs' attorney]: Again, not my question.</p> <p>Q. My question is: Assuming this information is accurate, would that have been important for you to know?</p> <p>[Bard's attorney]: Same objection.</p> <p>A. So it would have been important to me that Janet know, that Bard be aware, if we weren't already.</p>
280:13-25	<p>A. -- caval interruption was never an open -- well, I shouldn't say never. I guess they would ligate the vena cava, but -- so the standard of care before vena cava filters was pretty rudimentary medicine.</p> <p>Q. Yeah. But see, I'm going to move to strike that as nonresponsive because we were on the same page. You were responding directly to my question, but now you editorialized it.</p>

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	A. Well, you're -- my only problem was you were starting to talk about open surgery for -- it doesn't compute with vena cava filters.
292:12-23	<p style="text-align: center;">292</p> <p>12 [Plaintiffs' Attorney]: Okay. Had anybody</p> <p>13 from Bard ever communicated to you that between</p> <p>14 2003 and 2004 there were 29 adverse events that</p> <p>15 caused serious injury or death to patients?</p> <p>16 [Bard Attorney]: Object to the form.</p> <p>17 A. It's -- it's --</p> <p>18 Q. [Plaintiffs' Attorney]: By the Recovery</p> <p>19 filter?</p> <p>20 [Bard Attorney]: Same.</p> <p>21 A. And the date on this -- do I see a</p> <p>22 date? '04. So this was 13 years ago, 12 years</p> <p>23 ago. I don't recall. But I would be surprised if</p> <p>24 I wasn't notified of these things.</p> <p>25 Q. [Plaintiffs' Attorney]: So you think if this</p> <p style="text-align: center;">293</p> <p>1 happened that you would have been notified?</p> <p>2 A. Particular -- yes, the deaths. I</p> <p>3 think we were pretty --</p> <p>4 Q. How were you notified?</p> <p>5 A. Like, for instance, the Miami thing.</p> <p>6 I don't remember how I heard about the Miami</p> <p>7 death. I don't know where that fell into here,</p> <p>8 but I know there was a death in Miami. So we</p> <p>9 heard about them.</p> <p>10 Q. Did you receive a report from Bard?</p> <p>11 [Bard Attorney]: Object to the form.</p> <p>12 A. No. But I don't remember if there</p> <p>13 were conference calls. Because one of these</p> <p>14 things, you realize, is if these things were</p> <p>15 happening, the field becomes aware of them. Like</p> <p>16 this rep became aware. This rep would tell that</p> <p>17 rep. Then it gets out of control.</p> <p>18 Can I answer your question?</p> <p>19 Q. [Plaintiffs' Attorney]: You didn't.</p> <p>20 [Bard Attorney]: He is trying to.</p> <p>21 Q. [Plaintiffs' Attorney]: Here is my question:</p> <p>22 Did you prepare -- did you receive a written</p> <p>23 report?</p> <p>24 That was my question.</p> <p>25 A. I don't recall.</p> <p style="text-align: center;">294</p> <p>1 Q. Okay. What would the report -- what</p>

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	<p>2 would you expect it to be called, if there was</p> <p>3 such a report that was prepared and provided to</p> <p>4 the sales force?</p> <p>5 [Bard Attorney]: Object to the form.</p> <p>6 A. Field update.</p> <p>7 Q. [Plaintiffs' Attorney]: So somewhere in Bard</p> <p>8 you would expect that, if we requested, we could</p> <p>9 get field update reports that reflected all the</p> <p>10 adverse events that Bard was aware of that was</p> <p>11 provided to the sales force?</p> <p>12 [Bard Attorney]: Object to the form.</p> <p>13 A. Are you saying you're going to ask</p> <p>14 Bard for --</p> <p>15 Q. Sure.</p> <p>16 A. I don't know that it ever existed.</p> <p>17 I'm just saying --</p> <p>18 Q. No, no. You know what? Do you -- are</p> <p>19 you aware of a document?</p> <p>20 A. No. But this -- this information</p> <p>21 wouldn't have been -- we would have known about</p> <p>22 these. I don't know how it would have gotten to</p> <p>23 me, but we would have known.</p>
325:11-328:18	<p>[Q.] You knew about the Recovery and you knew they were going to stop selling the Recovery at Bard; right?</p> <p>A. At this -- point of this time?</p> <p>Q. Yes.</p> <p>A. I knew we had a new filter coming.</p> <p>Q. And you knew Recovery, you were going to stop selling it?</p> <p>A. I don't know if I knew -- I don't remember -- because earlier in testimony it came up that Recovery was still available for a while. So I don't remember the whole transitioning.</p> <p>Q. No. With all due respect, stop.</p> <p>A. Well, when we launched Recovery, did G2 --</p> <p>Q. Stop.</p> <p>A. -- or G2 -- when we launched G2, did Recovery go away? I don't remember.</p> <p>Q. Let me finish my question and I think you can answer it.</p> <p>A. Okay.</p>

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	<p>Q. I'm going by your words. "I know we aren't going to have it for much longer." You knew the Recovery was coming to an end?</p> <p>A. Well, I was speaking about removability of Recovery. I knew we weren't going to have that very much longer, I think.</p> <p>Q. You knew a new filter was coming, and you knew that Recovery was the removable filter; right?</p> <p>A. Yeah. The new filter did not have that indication.</p> <p>Q. Okay.</p> <p>A. So that's what would be a little weird.</p> <p>Q. All right. Let's just be fair about reading this.</p> <p>A. Okay.</p> <p>Q. Were you aware that sales of Recovery were going to stop at some point in time?</p> <p>A. I'd have to see what the frequently asked questions were that were attached to this. I think that that's what this was about, but I don't recall.</p> <p>Q. Just based upon your recollection, knowing the G2 was coming out, knowing that the Recovery was stopped, you knew it was going to happen before it happened; right?</p> <p>A. I don't know that I did. I really don't. Because that's a decision that was made in another room.</p> <p>Q. How did you learn about it?</p> <p>A. That Recovery was being taken away? I don't recall how I learned.</p> <p>Q. Well, was there ever a period of time where you had the two, you could sell the Recovery as an optional removable filter and you had the G2 for a permanent filter?</p> <p>A. That's what I -- I don't remember -- I think there was a period of time where there was an overlap. I don't remember.</p> <p>Q. So you think, seem to recall that there was a time where the company was still, through the sales force, promoting the Recovery filter when the G2 was on the market as a permanent filter?</p> <p>A. I don't recall -- I can't --</p> <p>Q. Is that your best recollection?</p> <p>A. I can't recall what the -- what the cadence was, because we didn't pull Recovery. So it would have still been available.</p> <p>Q. All right.</p> <p>A. And you're telling me we didn't sell it. So that's what I'm trying to --</p>

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	<p>Q. Well, I'm not telling you anything. Let me just make sure I can get the question.</p> <p>A. Yeah.</p> <p>Q. There was a period of time where you were still promoting the Recovery and you started to promote the G2; fair?</p> <p>A. Fair. I think so. That's my recollection, but I may be wrong.</p>
349:18-350:12	<p style="text-align: center;">349</p> <p>18 [Plaintiffs' Attorney]: Now go to page 614.</p> <p>19 A. Yes.</p> <p>20 Q. These are MDRs for February 2010.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know what an MDR is?</p> <p>24 A. Yeah. We discussed it was a medical</p> <p>25 device report, or we discussed it earlier.</p> <p style="text-align: center;">350</p> <p>1 Q. Did you ever receive a report in this</p> <p>2 form that we're looking at?</p> <p>3 A. No. But honestly, in looking at it,</p> <p>4 I'm glad that it was in front of Jim. He was our</p> <p>5 president; right?</p> <p>6 Q. That wasn't my question.</p> <p>7 A. I'm sorry.</p> <p>8 Q. Don't reinterpret my question. Don't</p> <p>9 change my question. I'm running out of time.</p> <p>10 Did you ever get a report in this</p> <p>11 format, yes or no?</p> <p>12 A. No.</p>
354:8-361:8	<p style="text-align: center;">349</p> <p>18 [Plaintiffs' Attorney]: Now go to page 614.</p> <p>19 A. Yes.</p> <p>20 Q. These are MDRs for February 2010.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know what an MDR is?</p> <p>24 A. Yeah. We discussed it was a medical</p> <p>25 device report, or we discussed it earlier.</p> <p style="text-align: center;">350</p> <p>1 Q. Did you ever receive a report in this</p> <p>2 form that we're looking at?</p> <p>3 A. No. But honestly, in looking at it,</p> <p>4 I'm glad that it was in front of Jim. He was our</p>

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	<p>5 president; right?</p> <p>6 Q. That wasn't my question.</p> <p>7 A. I'm sorry.</p> <p>8 Q. Don't reinterpret my question. Don't</p> <p>9 change my question. I'm running out of time.</p> <p>10 Did you ever get a report in this</p> <p>11 format, yes or no?</p> <p>12 A. No.</p>
	<p style="text-align: center;">359</p> <p>2 Q. That's about 12 adverse events</p> <p>3 reported in February 2010 regarding the G2 filter.</p> <p>4 A. Yeah.</p> <p>5 [Bard's attorney]: Object to the form.</p> <p>6 A. I mean, yes, they look like adverse</p> <p>7 events.</p> <p>8 Q. [Plaintiffs' Attorney]: Okay.</p> <p>9 A. I don't know if there were patient</p> <p>10 harm in any of those. That's the one thing I</p> <p>11 haven't had a chance to read in that time period</p> <p>12 there.</p> <p>13 Q. Hold it. Stop. They're called events</p> <p>14 on this report; right?</p> <p>15 A. Yes.</p> <p>16 Q. There's 12 events showing that the</p> <p>17 filter did something it was not supposed to do;</p> <p>18 true?</p> <p>19 [Bard's attorney]: Object to the form.</p> <p>20 A. Yes.</p> <p>21 Q. [Plaintiffs' Attorney]: Concerning to you as</p> <p>22 regional manager that that many events would</p> <p>23 happen in a one-month period?</p> <p>24 [Bard's attorney]: Object to the form.</p> <p>25 A. I don't have something to compare it</p>
	<p style="text-align: center;">360</p> <p>1 to; I'm sorry to say. You know, there are other</p> <p>2 device complaints on here as well that we might --</p> <p>3 Q. [Plaintiffs' Attorney]: I'm not going there.</p> <p>4 A. Well --</p> <p>5 Q. Just tell me yes or no. Are you</p> <p>6 concerned about 12 events in one month? If you're</p> <p>7 not, just say I'm not.</p> <p>8 A. Well, look. I think we would be</p> <p>9 concerned about one complaint.</p>

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	<p>10 Q. Well, if you're concerned about 1, 11 then you certainly would be very concerned about 12 12; right?</p> <p>13 A. We would -- sure.</p> <p>14 Q. Thank you.</p> <p>15 Did you ever receive a compilation 16 like this as regional manager?</p> <p>17 A. No. But the --</p> <p>18 Q. Did you? Yes or no.</p> <p>19 A. To my earlier comment, Jim Beasley, it 20 looks like he sends it to Tim Ring and John 21 Weiland. These are the guys who would want to 22 know.</p> <p>23 [Plaintiffs' Attorney]: I got to move to 24 strike, and I think everybody would agree that you 25 go beyond the question.</p> <p style="text-align: center;">361</p> <p>1 Q. [Plaintiffs' Attorney]: Did you ever receive a 2 report in this form as a regional manager? Yes or 3 no?</p> <p>4 [Bard's attorney]: He's already answered 5 that question several times.</p> <p>6 [Plaintiffs' Attorney]: Stop it.</p> <p>7 A. I don't recall receiving this 8 document. This is Jim's report.</p>
365:8-25	<p>4 [Plaintiffs' Attorney]: Did you in sales 5 ever have meetings with people from -- people who 6 were responsible to track and trend complaints to 7 find out what they were learning?</p> <p>8 A. I don't recall. And in 2010 you -- 9 what we're glossing over a little bit, we're 10 focused on filters, but there was a lot going on 11 with the organization that we were focused on as 12 well.</p> <p>13 So I'm not saying these weren't 14 important things, but over time we'd become bigger 15 and bigger, and I would hope that we'd have a team 16 of people. And my expectation was there was a 17 team that was working on filters while all the 18 other projects were running. Again, this is out 19 of my scope.</p> <p>20 Q. You're eating up my time by telling me 21 nonresponsive information.</p>

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	<p>22 Well, I was giving you some --</p> <p>23 Q. I'm not interested.</p> <p>24 A. -- kind of where my mind was, since I</p> <p>25 don't recall this.</p>
374:7-375:4	<p>2 [Plaintiffs' Attorney]: Next, filter limb detached and was</p> <p>3 found in the patient's heart.</p> <p>4 That's a serious injury; right?</p> <p>5 A. Yes.</p> <p>6 [Bard's attorney]: Object to the form.</p> <p>7 A. It could be. Again, these are --</p> <p>8 you're asking me -- so at this time I was a</p> <p>9 regional sales manager, and I -- I'm certain --</p> <p>10 and I'm going to have to -- you're asking me a lot</p> <p>11 of questions about medicine that I can't tell you.</p> <p>12 Doctors put stints in hearts. So this</p> <p>13 was certainly not an ideal thing for the filter to</p> <p>14 have a leg in someone's heart. And I'm not coarse</p> <p>15 in saying that it wasn't. I would not want -- I</p> <p>16 would never want a vena cava filter. I don't want</p> <p>17 anyone in my family to have one, because you have</p> <p>18 a lot of sickness that's leading to that.</p> <p>19 What I will -- just -- what I don't</p> <p>20 know by reading this is the filter was tilted at</p> <p>21 90 degrees.</p> <p>22 Q. [Plaintiffs' Attorney]: Right.</p> <p>23 A. Did it get tilted when the physician</p> <p>24 was trying to retrieve it? These are things we</p> <p>25 don't know.</p> <p>375</p> <p>1 Q. You know what. See. You're</p> <p>2 nonresponsive. And when you do that, you make it</p> <p>3 very difficult --</p> <p>4 A. I'm speaking. That's responding.</p> <p>5 Q. No. No. And your lawyer knows you</p> <p>6 shouldn't be doing that, too.</p> <p>7 [Bard's attorney]: That's not true.</p> <p>8 Q. [Plaintiffs' Attorney]: And, you know, it's</p> <p>9 been a problem throughout the deposition. And</p> <p>10 I've tried to keep it simple and ask you direct</p> <p>11 questions. And when you ramble on and you're</p> <p>12 nonresponsive, you're interfering with my ability</p> <p>13 to ask questions for my clients, okay?</p> <p>14 [Bard's attorney]: He's simply trying to</p>

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	<p>15 answer the questions.</p> <p>16 [Plaintiffs' Attorney]: No. No.</p> <p>17 THE DEPONENT: I'm here to help you,</p> <p>18 sir. I'm not here to interrupt.</p> <p>19 Q. [Plaintiffs' Attorney]: Well, to me, it</p> <p>20 seems like maybe we need somebody to tell me if</p> <p>21 I'm right or tell you if you're wrong. But I am</p> <p>22 asking you to answer my questions. I have a right</p> <p>23 to get answers to my questions, and I have a right</p> <p>24 to control how the witness answers my questions,</p> <p>25 and I have a right to get the questions out the</p> <p style="text-align: center;">376</p> <p>1 way I want to.</p> <p>2 Now, as you look at --</p> <p>3 [Bard's attorney]: He's entitled to --</p> <p>4 [Plaintiffs' Attorney]: Stop it.</p> <p>5 [Bard's attorney]: -- explain his answers,</p> <p>6 and you know that.</p> <p>7 [Plaintiffs' Attorney]: No, he's not.</p> <p>8 [Bard's attorney]: And telling him that</p> <p>9 he's not entitled to do so and acting as if he's</p> <p>10 doing something wrong by trying to completely</p> <p>11 answer your question is completely improper.</p> <p>12 [Plaintiffs' Attorney]: No. And you know the</p> <p>13 difference between being argumentative and</p> <p>14 evasive, and you know what's happening here.</p> <p>15 Q. [Plaintiffs' Attorney]: All these things on</p> <p>16 page 493 --</p> <p>17 A. Yes, sir.</p> <p>18 Q. -- are those things that you're proud</p> <p>19 of when you look at how this filter performed?</p> <p>20 A. No.</p> <p>21 [Plaintiffs' Attorney]: Okay. Let's take 5</p> <p>22 minutes.</p> <p>23</p>
<p>388:20-389:21; 413:20-414:17 [State/Fed Coordination]</p>	<p style="text-align: center;">388</p> <p>3 Q. And if in 2010 Bard was receiving</p> <p>4 monthly reports that included that the G2 filter</p> <p>5 was perforating and tilting and migrating, that</p> <p>6 information would be helpful to you and your sales</p> <p>7 force to explain to physicians why the new model</p> <p>8 was an improvement and safer; fair?</p> <p>9 [Bard Attorney]: Object to the form.</p> <p>10 A. I think we've answered. We've talked</p> <p>11 about this. So I think -- it is important that</p>

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	<p>12 the people that are on this email and the people 13 that are developing and creating products, one, 14 are tracking this. So I think that's important 15 that we know what our complaint history is and 16 what our problems are so we can fix it. 17 Certainly important for the field to 18 know when there's an event that we need to be 19 aware of, for sure. 20 [Bard Attorney]: Mark. Mark, we're over 21 the time limit. I've been waiting to see if you 22 were going to ask something new, to give a little 23 leeway if you had something else, but we're just 24 reploting.</p>
	<p>25 [Plaintiff Attorney]: No, we're not. 389</p>
	<p>1 [Bard Attorney]: -- the same ground. 2 So --</p>
	<p>3 [Plaintiff Attorney]: I'm talking about a 4 relevant time and a relevant filter that's 5 relevant to the Claire Austin, which is the state 6 case, which I believe was cross-noticed here.</p>
	<p>7 [Bard Attorney]: Okay. Well, our 8 position, as you know, is that the time limit of 9 the MDL applies to the deposition, and we're 10 beyond that.</p>
	<p>11 [Plaintiff Attorney]: Are you saying it 12 applies even to state court cases that are 13 cross-noticed?</p>
	<p>14 [Bard Attorney]: I'm not going to get 15 into the weeds with you on that. Your firm is 16 plaintiff's liaison counsel in the MDL and so -- 17 as you're well aware. So you well know the rules.</p>
	<p>18 [Plaintiff Attorney]: I can wrap this up in 19 10 minutes.</p>
	<p>20 [Bard Attorney]: I'm not giving 10 21 minutes. I'm not giving 10 minutes. You just 22 spent the last ten minutes asking the same 23 question you asked multiple times throughout the 24 day. We're not giving 10 more minutes.</p>
	<p>413</p>
	<p>20 [Bard Attorney]: The deposition's over, 21 and here's why. I think you did this 22 intentionally.</p>
	<p>23 [Plaintiff Attorney]: Did what?</p>

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	<p>24 [Bard Attorney]: I think you put us in 25 this position intentionally because the last 10 414 1 minutes of your questions were repetitive of what 2 you had plowed through for the 30 minutes 3 before -- 4 [Plaintiff Attorney]: No. 5 [Bard Attorney]: -- when he told you it 6 was a document he wasn't familiar with and he'd 7 never seen before. 8 [Plaintiff Attorney]: My questions were 9 relevant to the Claire Austin case and the time 10 period when she had to -- 11 [Bard Attorney]: I'm not saying they 12 were irrelevant to anything. I'm saying I think 13 you deliberately wasted the time. 14 Can you unplug my cord? 15 [Plaintiff Attorney]: All right. So you are 16 stopping this deposition; is that right? 17 [Bard Attorney]: I am.</p>
394:3-409:5 [Bard Direct Examination]	<p>394 3 Mr. Sullivan, we've met before. I'm 4 Brandee Kawalzyk, counsel for Bard and counsel for 5 you as well. 6 A. Yes. 7 Q. And I have a few questions in 8 follow-up to what you were asked today. 9 Just in order to give a little bit 10 more kind of context of who you are and 11 everything, could you tell us where you grew up? 12 A. I grew up in Kansas City. 13 Q. Have you lived in Kansas City all your 14 life? 15 A. Yes. 16 [Plaintiffs' attorney]: Objection. Form. 17 Q. [Bard's attorney]: And do you have 18 family here? 19 A. I do. 20 Q. Are you married? 21 A. I am. 22 Q. Do you have a lot of family here? 23 A. I have two brothers and a sister. I'm 24 sorry. 25 Q. Do you have kids?</p>

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1	A. I do have three kids.
2	Q. Okay. And --
3	A. The reason why I paused on the
4	brothers is I have a brother that passed away. So
5	I usually say three brothers and a sister, but I
6	wanted to be accurate here.
7	[Bard attorney]: I'm sorry about that.
8	THE DEPONENT: That's okay.
9	[Plaintiffs' attorney]: I am sorry about that.
10	Q. [Bard attorney]: How old are your
11	kids?
12	A. My oldest son is 21, my middle
13	daughter is 20, and my youngest is 16. And I've
14	been married for 24 years.
15	Q. And are your oldest two in college?
16	A. Jack is in the Army. He's a sophomore
17	in the military. Christine is a junior in
18	college, and Kate is a junior in high school.
19	Q. Would you describe your role as a
20	regional manager during your time at BPV?
21	[Plaintiffs' attorney]: Object to the form of
22	the question.
23	A. Sure. So it -- by the time I left, I
24	was managing one rather large customer, as I
25	discussed earlier today, but essentially my role
	396
1	was to assist managers and their reps and --
2	throughout our entire portfolio. Ironically,
3	there was a lot of time spent interviewing and
4	backfilling or expanding. So it was a lot of
5	talent, acquisition.
6	Really, we looked at it this way. We
7	acquire talent, we try to develop and retain our
8	talent. So I was kind of involved with that.
9	Q. [Plaintiffs' attorney]: And you mentioned
10	throughout the entire portfolio.
11	What do you mean by that?
12	A. So with the time that I -- throughout
13	the time I was there, we had multiple buckets of
14	products, a PTA, filters, stents, surgical grafts.
15	By the time I left we had ports, dialysis,
16	catheters. Biopsy was mixed in there. Some
17	drainage. So there was a number of products in
18	the portfolio.

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	<p>19 Q. During your time at Bard, you were</p> <p>20 always in the sales department?</p> <p>21 A. Yes.</p> <p>22 Q. And did your responsibilities ever</p> <p>23 include creating and approving documents like IFUs</p> <p>24 or brochures or other material that was provided</p> <p>25 to physician customers?</p> <p style="text-align: center;">397</p> <p>1 [Plaintiffs' attorney]: Form.</p> <p>2 A. No.</p> <p>3 Q. [Bard attorney]: You would rely on</p> <p>4 others to create those type of documents?</p> <p>5 A. Yes.</p> <p>6 Q. Such as marketing?</p> <p>7 A. Marketing, for sure.</p> <p>8 Q. Did your responsibilities ever include</p> <p>9 coming up with tests for IVC filters?</p> <p>10 A. They did not.</p> <p>11 Q. That would be the responsibility of</p> <p>12 another department at Bard?</p> <p>13 A. Yes.</p> <p>14 Q. Was that R&D?</p> <p>15 A. R&D. Probably, yes, at the time.</p> <p>16 Q. Did your responsibilities ever include</p> <p>17 reviewing scientific literature to understand the</p> <p>18 IVC?</p> <p>19 A. Understand the cable dynamics kind of</p> <p>20 thing?</p> <p>21 Q. Right.</p> <p>22 A. No. Not at any time.</p> <p>23 Q. Whose responsibility would that have</p> <p>24 been?</p> <p>25 A. I would put that in R&D or wherever</p> <p style="text-align: center;">398</p> <p>1 our technical engineers, et cetera, were housed.</p> <p>2 Q. Did your responsibilities ever include</p> <p>3 determining what the complication rates were for</p> <p>4 Bard's IVC filters?</p> <p>5 A. No, I did not.</p> <p>6 Q. That would be the responsibility of</p> <p>7 another department at Bard?</p> <p>8 A. Yes.</p> <p>9 Q. Whose responsibility would that have</p> <p>10 been?</p> <p>11 [Plaintiffs' attorney]: Form. Foundation.</p>

Page/Line	Sullivan depo text
	<p>12 A. So quality -- I think there may have</p> <p>13 even been a complaint handling department under</p> <p>14 quality.</p> <p>15 Q. [Bard attorney]: You had no</p> <p>16 responsibilities for evaluating reports of</p> <p>17 complaints with IVC filters?</p> <p>18 A. No, I did not.</p> <p>19 Q. And that's field assurance or quality</p> <p>20 assurance as well?</p> <p>21 A. Yes. Field assurance, yes.</p> <p>22 Q. Did you have any responsibility for</p> <p>23 conducting tracking or trending of complaint</p> <p>24 rates?</p> <p>25 A. I did not.</p> <p style="text-align: center;">399</p> <p>1 Q. Who would have -- whose responsibility</p> <p>2 would that have been?</p> <p>3 A. Field assurance, quality, probably a</p> <p>4 whole team of folks would keep on eye on that.</p> <p>5 Q. As a regional sales manager, did you</p> <p>6 expect to receive a report of every single</p> <p>7 complication associated with a Bard IVC filter?</p> <p>8 A. As discussed, it is something that --</p> <p>9 [Plaintiffs' attorney]: I'll object to the form</p> <p>10 of the question.</p> <p>11 Excuse me. Go ahead.</p> <p>12 THE DEPONENT: That's okay.</p> <p>13 A. It is something that we, in the</p> <p>14 field -- I can recall wanting to know, but there</p> <p>15 were others, obviously, that needed to know that.</p> <p>16 So the information was all gathered. It's just</p> <p>17 how it was delivered to us, I don't recall.</p> <p>18 I don't know that I answered your</p> <p>19 question entirely. Did I expect to receive that</p> <p>20 information? I would have liked to receive that</p> <p>21 information, sure.</p> <p>22 Q. [Bard attorney]: Were you responsible</p> <p>23 for communicating that information with FDA?</p> <p>24 A. No, I was not.</p> <p>25 Q. Who would have been responsible for</p> <p style="text-align: center;">400</p> <p>1 that?</p> <p>2 A. I don't -- I don't know which</p> <p>3 department that would have been. Probably</p> <p>4 regulatory, political affairs, maybe. I don't</p>

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	<p>5 know what we named our department then that dealt</p> <p>6 with the FDA.</p> <p>7 Q. Right.</p> <p>8 A. It was not sales.</p> <p>9 Q. You recall being asked about the</p> <p>10 Recovery filter IFU earlier today --</p> <p>11 A. Yes.</p> <p>12 Q. -- when Mr. DeGreeff was asking you</p> <p>13 questions?</p> <p>14 A. I do.</p> <p>15 Q. And he asked you about a document</p> <p>16 called a Dear Doctor letter?</p> <p>17 A. Yes.</p> <p>18 Q. He asked you about a couple of filter</p> <p>19 brochures?</p> <p>20 A. Yes.</p> <p>21 Q. You were asked about the warnings and</p> <p>22 complications that were listed in the IFU?</p> <p>23 A. Yes.</p> <p>24 Q. And information about warnings or</p> <p>25 complications that were in the Dear Doctor letter</p> <p style="text-align: center;">401</p> <p>1 as well?</p> <p>2 A. Yes.</p> <p>3 Q. Was it your role to decide the</p> <p>4 information that goes into the IFU?</p> <p>5 A. No.</p> <p>6 Q. Or to decide what information goes</p> <p>7 into a Dear Doctor letter?</p> <p>8 A. No.</p> <p>9 Q. You relied on others to make those</p> <p>10 decisions?</p> <p>11 A. Yes. Again, I relied on another whole</p> <p>12 team of -- or department.</p>

Maureen Uebelacker, 8/9/2016

Page/Line	Uebelacker depo text
157:3-165:3	<p>Q. Would you agree with me that Bard PV has a responsibility to know with what frequency its IVC filter products migrate and produce injury?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A. Repeat that question, please?</p>

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	<p>Q. Would you agree with me that Bard PV has a responsibility to know with what frequency its IVC filter products migrate and produce injury?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A. I think that Bard has a responsibility to ensure patient safety, and to gather all the knowledge that they need in order to give the information over to clinical teams that would determine whether or not something is causing patient injury or not.</p> <p>Q. I'm going to move to strike as nonresponsive, and ask if you would agree with me that Bard has a responsibility to know with what frequency its IVC filter products migrate and produce injury.</p> <p>[Bard's attorney]: Objection to form.</p> <p>A. I think Bard gathers information on filter migration, we spoke to that before, and that information is from our complaint files, and we've produced that information in order to share it with the teams to review. I think the way your question is worded, it's only related to injury, and I'm not understanding the last part of your question.</p> <p>Q. I'm going to move to strike as nonresponsive. I'm not asking what Bard does do.</p> <p>A. Okay.</p> <p>Q. I'm asking about what, as the Director of Post-Market Quality, you believe Bard has a responsibility to do, in terms of post-market surveillance. Are you following that?</p> <p>A. Yes.</p> <p>Q. Okay. Does Bard have a responsibility to know with what frequency its IVC filters are migrating and producing injury to filter patients?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A. Bard has a responsibility to know information about migration, and migration is also a known complication of IVC filters, not only Bard filters. So we produce the information on migration. That's the best, you know, answer I could give you.</p> <p>Q. Does Bard have a responsibility to know at what frequency the migrations are causing patient injury?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A. I think I've answered that. We do provide information on the data. And we do have a responsibility to look at all of our products.</p> <p>Q. Move to strike as nonresponsive. Does Bard have a responsibility to know with what frequency its IVC filters are migrating and injuring the patient?</p>

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	<p>[Bard's attorney]: Objection to form.</p> <p>A. I can't answer that question. They do have responsibility to understand the frequency of migration, and they do understand that frequency of migration. Migration is also a known outcome of IVC filters. I think the part I'm objecting to is, you are assuming there's injury, and there are several reasons for migration that happen clinically, not only due to a filter, but due to the human anatomy and several other reasons why a filter could migrate. So maybe that's why I can't answer your question totally.</p> <p>Q. My question is asking if Bard has a responsibility to know how frequently its filters are migrating and causing injury to the patient.</p> <p>[Bard's attorney]: Objection to form.</p> <p>Q. Where the filter migration is causing an injury to the patient. You understand that can occur, true?</p> <p>A. I understand that can occur.</p> <p>Q. When it occurs, would you agree with me that Bard has a responsibility to identify it?</p> <p>[Bard's attorney]: Objection to form.</p> <p>Q. If -- let me put it this way. When it occurs -- strike the question. Does Bard have a responsibility to know how frequently that occurs?</p> <p>A. How frequent migration occurs?</p> <p>[Bard's attorney]: Objection to form.</p> <p>Q. Causing an injury.</p> <p>A. Bard does have a responsibility to understand their failure modes. Migration is a failure mode of an IVC filter, not only Bard filters, but all filters. That is a known complication of an IVC filter. There are several reasons why migration can happen. If there were an injury, Bard would know that information and record it in a complaint file, but it doesn't necessarily mean that we would understand the cause of that injury, if that helps me explain my answer to you.</p> <p>Q. Does Bard have a responsibility to try to determine how frequently its IVC filters are causing injury to filter patients?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A. I think I've answered that to the best of my knowledge, I'm sorry.</p> <p>Q. I don't believe you have. I apologize if you believe you have. You've changed it. I think you've answered different questions. You've explained some of why you're not answering it. So even if you believe you have answered it, I apologize. I believe it's an important question. Does Bard</p>

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	<p>have a responsibility to try to determine how frequently its IVC filters are causing injuries to patients?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A: I don't believe, in my opinion, that migration is the only -- is the result of the injury all of the time. So I don't -- I can't answer that to you. I think I've explained, there are several reasons for migration of a filter. So that's maybe why I can't directly answer your question. I'm sorry.</p> <p>Q. Does Bard make any effort to determine how frequently its IVC filters cause injury to patients?</p> <p>A. Bard makes an effort to understand the frequency of migration for all of its filter products, and we also look at patient outcomes to see if there is an injury, so that we could, of course, report it through regulatory reporting, and also look at the information to see if there is anything that we need to take action on.</p> <p>Q. How frequently has Bard determined that its IVC filters have caused an injury to a patient?</p> <p>A. I wouldn't know that.</p> <p>Q. Have you been ever -- have you ever been asked -- strike the question. Have you ever been asked to review the data within Bard's post-market surveillance system to find an answer to that question?</p> <p>A. We look at all the failure modes for IVC filters. We look at migration as one of them, I've explained. We look at patient outcomes. We look to see if there is clinical significance to the information provided to us. That's what we've done.</p> <p>Q. I'm not asking what you're looking for. I'm asking if you've ever been asked to look for something, okay? That's a little different. Has anybody at Bard ever asked you to try to determine how frequently Bard's IVC filters have caused injuries to patients?</p> <p>A. Can you give me a specific injury you're talking about?</p> <p>Q. Let's keep it broad, to wonder if anybody's ever asked you to do that.</p> <p>A. Okay. We look at patient outcomes --</p> <p>Q. I understand --</p> <p>A. -- and --</p> <p>Q. -- but I'm asking if someone's come to you with my question, and they may not have, but I'm entitled to know if they have.</p> <p>A. Right, well, we provide data as we get requests, so --</p> <p>Q. I'm not asking that.</p>

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	<p>A. But I'm saying, you're asking if we provided the data on frequency, and if somebody asked us for a frequency on migration, we would give them that information.</p> <p>Q. I'm not asking that.</p> <p>A. Okay, sorry.</p> <p>Q. That's okay. I'm asking something different. I'm asking if anybody has come into your office, or made a request to you, by e-mail or any other way, to determine, based on Bard's internal information, how frequently Bard filters have caused an injury to a patient.</p> <p>A. In my office, come to me specifically?</p> <p>Q. I broadened it.</p> <p>A. Okay.</p> <p>Q. I broadened it to everything.</p> <p>A. Okay.</p> <p>Q. On purpose. I don't want -- if someone sent you an e-mail, I don't wanting you to omit it. So that's why I'm asking, has anyone at Bard ever asked you to determine how frequently an IVC filter has caused injury to a patient?</p> <p>A. We have reported serious injuries, when people ask us for serious injury --</p> <p>Q. Not my question.</p> <p>A. -- right, for MDR.</p> <p>Q. Right. I didn't ask serious injury.</p> <p>A. Right, there's all different types of patient injuries. So your category is so broad.</p> <p>Q. Maybe that's why no one's ever asked.</p> <p>A. Maybe.</p>

John A. DeFord, Ph.D., 6/2/2016

Page/Line	DeFord depo text
119:15 – 120:13	<p>Q. Was that doctor informed that there was approximately one death per month following the migration incident of February 2004 –</p> <p>A. I --</p> <p>Q. When he made those statements?</p>

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	<p>A. -- I don't recall the exact details, but I'm confident that he had knowledge of any complications, which, you know, we're talking about here -- and each one of these are tragic events that are happening in a sick patient population in very small numbers, although, as I said, every one of these is a significant event. That, as you can see by these documents, Bard took a lot of time and care trying to analyze each one of these and understand the situations behind them to see if there were specific issues with the product or ways to improve the product.</p>
121:1 – 122:6	<p>[Q.] At what point did Bard think it was appropriate to take the device off the market and save lives?</p> <p>[Bard's attorney]: Objection to form.</p> <p>A: Well, first off, I disagree with your comment that the device is killing people. The disease is killing people. The device failed to prevent it. That's a very different thing. The device is still adding value. It couldn't stop a massive thrombus, just like your seatbelt can't stop a train from hitting you and destroying your car. This thing was -- these kind of events were beyond anything that Bard or anyone in the industry to my knowledge knew about. And -- and so it was being evaluated very vigorously. As you can see by this documentation, we were looking at it very closely, very carefully, and trying to understand every single event to put the very best products on the market and keep them as safe as they possibly could be and keep patients safe.</p>
156:15 – 157:8	<p>Q. So in your opinion, the sales reps in 2004 and before the product was placed on hold in 2005 should have been made aware of these deaths and other migration events that were occurring with the Recovery filter; is that right?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. Well, again, I think there's -- there was certainly no attempt to not share the information. There were lots of communications within the sales organization. I'm confident in my recollection. And I don't know whether they resulted in e-mails on a routine basis, but I'm sure there was communication.</p>
227:12 – 231:17	<p>[Q.] And yet you knew in -- Bard knew in 2004 the need for retrieving an IVC filter.</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. I -- I don't understand -- and to the extent I understand the question, I guess I'd say no. IVC filters were designed, so the Recovery was designed to be retrievable. We thought and still believe that that added significant value to the patient with the ability to retrieve it. But we didn't specifically say, you must retrieve it or you should retrieve it, although my belief is that that was common knowledge: That this is a retrievable device. If you don't</p>

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	<p>need it anymore, why are you leaving it in? It's designed specifically so you can take it out.</p> <p>Q. Well, it obviously wasn't common knowledge because the rates of retrieval were so terribly low; correct?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. I disagree. I don't think it was a fact of not being common knowledge. I think it was more a function of the way these patients are treated. So at that particular time in history, interventional radiologists were the primary placers. Interventional radiologists don't usually track the patient. The patient is referred to them for a filter placement by a surgeon or some other clinician, oncologist, for example. They place it and at that particular time, those patients wouldn't necessarily know to go back to the radiologist for retrieval. And so it kind of got lost in the system. It wasn't until later that better systems were devised to track those patients to be able to call them and get them back and have the product retrieved. So I don't think it was a matter of not common knowledge that the products were retrievable and could be retrieved or even should be retrieved. It was a matter of those patients weren't in a pool where they could be found to have them retrieved.</p> <p>Q. I'm not sure that's responsive to my question, but I'll let it stand. Where we are right now is, in 2004, December 2004, Bard was aware of the risk associated with allowing a retrievable filter to remain in dwelling for an extended period of time, was it not?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. Again --</p> <p>Q. This is just a yes or no answer.</p> <p>[Bard's attorney]: Objection.</p> <p>A. I'd like to say yes or no, but it's more complicated than that in that there was a body of evidence, small body of evidence, suggesting that -- that filters should be removed. This was back in 1998. That led to the development of some of the retrievable devices and so I don't think that -- at that time, my recollection is, at that time, there wasn't a sense that the devices must be retrieved or should be retrieved, but could be retrieved. And then clinicians understood that this technology, because of its retrievable nature, was such that if the risk was no longer there, you could take it out.</p>
297:19-300:5	<p>Q. My question was, do you know whether or not Bard told physicians that the devices that they were swapping out on the shelves of hospitals, that they called the next-generation Recovery device, was in fact not a retrievable filter like the Recovery device, but rather was only cleared for permanent implantation?</p>

Page/Line	DeFord depo text
	<p>A. I don't have specific knowledge, but I'm sure that Bard explained to customers that the device was designed as retrievable, was cleared as permanent, and that Bard was working toward a retrievable indication.</p> <p>Q. Okay. Because if Bard would have told the doctors that the G2, which had not been cleared to be retrievable, was just like the Recovery or in fact better than the Recovery, and intimated to the doctors or directly told them that they could go ahead and retrieve the device, that would have been off-label selling. Right?</p> <p>A. Well, technically, yes. I think there's -- the whole off-label promotion piece is a very complicated thing that I'm probably not an expert to discuss, but I understand there continues to be a lot of discussion around what's truly off label and what's -- and what's -- what can be said. So I don't know how to answer that exactly, but I can say that I'm confident, because Bard takes a very strong position on that, that Bard would have fully disclosed to physicians that the product was cleared with a permanent indication.</p> <p>Q. And I know you say you're sure that Bard did that, but if there are documents that refute that statement, you really don't have any -- you don't have any evidence that Bard did that, do you?</p> <p>A. Well, I --</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. I would say that in my experience with Bard -- maybe that's the better way to answer it -- in my experience with Bard and all of the interactions I've had with senior management and divisional management, Bard takes a very conservative and strict view on off-label promotion and has been -- and at least in my experience -- very diligent.</p>
410:3-411:17	<p>Q. So Bard's official statement in this document where they're asking you to report this to the world, where it says, quote, The findings of Nicholson et al regarding filters are not new. Multiple published peer-reviewed studies and case reports have previously described similar issues, these seven articles don't, in fact, do that.</p> <p>A. No, they do that, but they do more, and so my point is --</p> <p>Q. That's fine. Doctor --</p> <p>A. My point is --</p> <p>Q. Doctor, that's fine that they do more --</p> <p>[Bard's attorney]: Objection. You're interrupting him.</p> <p>[Plaintiffs' attorney]: No, I --</p> <p>[Bard's attorney]: He answered your question --</p>

Page/Line	DeFord depo text
	<p>[Plaintiffs' attorney]: He's had a whole day of going down the question. I just want the question answered. There's seven articles here --</p> <p>[Bard's attorney]: And he answered it and he can explain his answer.</p> <p>[Plaintiffs' attorney]: No, you can't, Richard.</p> <p>[Bard's attorney]: Yeah, you can.</p> <p>[Plaintiffs' attorney]: No, you can't. Until there's a question that he can -- it's a yes or no --</p> <p>[Bard's attorney]: We'll let Judge Campbell decide this if we need to. But move on.</p> <p>[Plaintiffs' attorney]: That's fine with me.</p>
429:7-430:21	<p>Q. Do you know if -- and then it goes on right after that -- first of all, did you -- do you remember talking to Mark from the Cleveland Clinic about getting Bard to support a large retrospective study to refute Nicholson?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. No. What this is saying is, Mark was suggesting, on his belief, based on his own experience, that he had data that he could pull together retrospectively; and if Bard would support it, he would do that study. My recollection is, I was suggesting to him not to do that, that it was better to do a prospective study.</p> <p>[Plaintiff's attorney]: Move to strike. I'll try the question again.</p> <p>Q. I know you -- you like to get your clarifications out, but we -- we have to do this in steps. My question was, do you recall Mark telling you that he thought he could get Bard to support a large retrospective study to refute Nicholson?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>Q.: Do you recall that?</p> <p>A. I recall him asking me if he could get Bard to do that and suggesting that he could through Jim Beasley.</p>
443:11-444:7	<p>Q. How much -- how many shares in the company do you currently have?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. I don't know.</p> <p>Q. It certainly goes to bias. I don't know if there's a --</p> <p>[Bard's attorney]: What?</p> <p>[Plaintiff's attorney]: I don't know -- is there a form objection; is that what you said?</p> <p>[Bard's attorney]: Yeah.</p>

Page/Line	DeFord depo text
	<p>[Plaintiff's attorney]: Okay.</p> <p>Q. You hold shares in the company; correct?</p> <p>A. Yeah. I have an approximate knowledge of the value of the shares I hold, but I don't -- I don't know the number of shares right now exactly.</p>
449:9-21	<p>Q. So you have no basis to say whether this was, in fact, a crisis plan or a potential one-day crisis plan; correct?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. Well, what I can say is, in my experience at Bard --</p> <p>Q. That's not my question, Doctor. I don't even want you to go down that -- Mr. North has plenty of time with you.</p>
459:2-22	<p>Q. Okay. So both of the folks that Pablo Morales trained under were both key opinion leaders of Bard that you had cited to me earlier in the deposition; correct? When I asked who were two of the key opinion leaders for Bard, you gave me those two names; correct?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. I believe I did, yeah, although I don't recall that Dan Clair was ever compensated or was a key opinion leader for Bard. He was a key opinion leader.</p> <p>[Plaintiffs' attorney]: It's remarkable how we always get to another issue. I wasn't talking about compensation at all.</p> <p>A. I'm sorry.</p>

Abtihal Maki Raji-Kubba

Page/Line	Raji-Kubba depo text
28:8-17	<p>[Q.] It's important for Bard to understand the environment in which the medical device is going to be used. Correct?</p> <p>A. It is important in every new product development. And every product, actually, that every available information is taken into account in -- while designing the product, so we can develop the right test methods and we can actually demonstrate that we -- we've shown that it can withstand the safety requirements. The environmental requirements.</p>
51:10-24	<p>Q. Bard could have, nothing prevented Bard from picking up the telephone and calling the -- the -- the interventional radiologists and the vascular surgeons at the hospitals that had patients where the implants were occurring, to do studies just like the one that was done at the Massachusetts General Hospital. Correct?</p>

Page/Line	Raji-Kubba depo text
	<p>A. I am aware that Bard, at certain points in time, sent Dear -- "Dear Doctor" letters to update clinicians on what was going on. I am aware that Bard logs every complaint received on the product. In the, basically to the FDA, so it's available in the public domain, so if anyone wanted to look at anything on Bard products, they can actually look up the MAUDE database.</p>
61:12-23	<p>Q. If somebody is walking around with a filter that is fractured, and they don't know about it, then it's not a complaint that you're investigating. Right?</p> <p>A. Filter fracture was reported in the original clinical trials, so it's -- it's not a new failure mode, it is not an a frequent failure mode, but it's not a new failure mode, and as part of the original device that was approved, there were incidents -- and they're spelled out in the instruction for use, so that is actually a well-known risk.</p>
68:10-20	<p>Q. In the patient, if there's a fracture, is that a good thing or a bad thing?</p> <p>[Bard's attorney]: Objection to the form.</p> <p>A. The -- so we design the product so it doesn't fracture under use conditions. It's a known, in the design FMEA, failure mode analysis, we identify it as a potential failure mode. We put test methods to test for it. And we stress the filter when we're testing it in the laboratory, to -- when we simulate use conditions, to demonstrate with a high level of confidence that it doesn't.</p>
94:3-95:4	<p>Q. And if the information -- if Bard had information of this -- of this nature concerning its products, one option that Bard had would be to do its own studies of this nature on patients to see what the prevalence was of these types of complications that we've been discussing. Right?</p> <p>A. I can't agree with that.</p> <p>Q. Bard could not have done its own study?</p> <p>A. I can't really agree one way or the other or comment on it.</p> <p>Q. Bard could have contacted the lead physicians at the different hospitals that were using the Bard products, and told them that there were concerns and could they undertake to do the investigation, and that Bard would support them. Bard could have done that. Right?</p> <p>A. Sir, do you have the number of the -- number of lead hospitals?</p> <p>Q. Bard didn't --</p> <p>A. I'm just asking you, sir, I don't know what number you're referring to, to comment whether it's reasonable, unreasonable, or in what context should they do that, since in -- Bard was fully transparent with the FDA and in constant communication about how to manage the situation, to make sure</p>

Page/Line	Raji-Kubba depo text
	that the agency was fully aware, and actually, you can't take field action without consulting with the FDA.
101:9-102:16	<p>Q. Now, .08 percent is much, much smaller than the fracture rates that have been reported in the medical literature when the actual patients were evaluated. Right?</p> <p>A. Which medical literature are you referring to?</p> <p>Q. The Hull paper, the Nicholson paper, and the Kalva paper. The three that we've looked at this morning.</p> <p>A. Okay. The caveat, the Nicholson there is a question about the accuracy. This is different. But I also don't know the specifics about the patient population at these centers. Just to step back, every -- every product they're -- there are multiple factors that affect the performance of a product. Number one is the patient itself -- the patients themselves. So are there specific unique conditions with the patient, whether it's anatomy, do they have a larger vena cava. Then another is where was the product placed. And then there is the overall patient demographic in terms of, again, as I said earlier, are they bariatric, are they geriatric, are they pediatric, all of that. These things come into play. So these centers, I don't have the specifics about their own patient population. So I don't know -- I don't, typically, as a scientist, I can't generalize. I can tell you the -- this number is for the total number of -- the way the rate is calculated is the way it's calculated with any medical devices in industry, truly, across all product lines. So the rate that you see in this e-mail the .08 is reflective of that.</p>

Appendix C:

Defendants' Responses to Interrogatories
Pursuant to Case Management Order Number 8

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' RESPONSES TO
INTERROGATORIES PURSUANT
TO CASE MANAGEMENT
ORDER NUMBER 8**

INTERROGATORY NUMBER 1:

Describe Bard's Corporate Structure?

RESPONSE

C. R. Bard, Inc. ("Bard") is a multinational developer, manufacturer, and marketer of medical technologies in a wide variety of product fields, including the fields of vascular, urology, oncology, and surgical specialties. Bard markets its products and services worldwide to hospitals, individual health care professionals, extended care facilities, and alternative site facilities.

1 Bard operates through multiple divisions, with each division focused on specific
2 product fields. Among those divisions is Bard Peripheral Vascular, Inc. ("BPV"),
3 headquartered in Tempe, Arizona. BPV focuses on the development and sale of surgical
4 and interventional devices for peripheral vascular patency. The division's product line
5 includes many different products, including inferior vena cava ("IVC") filters, carotid
6 shunts, central venous catheters, hemodialysis catheters, stents and stent grafts, and
7 vascular probes. BPV also includes discrete business units, such as Bard Biopsy Systems,
8 which specializes in cancer diagnostic devices, and Lutonix, Inc., which specializes in
9 drug coated balloon PTA catheters.

10 In 2002, BPV obtained FDA clearance of the company's first retrievable IVC filter,
11 the Recovery® Filter. That product was first commercially distributed in 2003. BPV has
12 subsequently developed later generations of retrievable IVC filters, including the G2®,
13 the G2®Express, the G2®X, the Eclipse®, the Meridian®, and the Denali® Filters. From
14 the beginning, and continuing until today, BPV is the division of Bard responsible for the
15 development of IVC filters. While Bard has sold a relatively small amount of its IVC
16 filters outside the United States, through non-Bard distributors and Bard International
17 Business Centers (IBCs), the vast majority of sales have occurred in the United States
18 through BPV. BPV is also primarily responsible for developing marketing materials for
19 its IVC filters, including for international purposes, and reviews and approves all
20 marketing materials. Similarly, as to international regulatory submissions and
21 registrations, BPV itself prepares the underlying documentation that is used to support
22 those submissions and registrations, although the distributors and IBC Centers may
23 actually file the documentation (or portions thereof) with the foreign regulatory body.

24 Bard's IVC filters are manufactured at Bard's Glens Falls Operations in Glens
25 Falls, New York. That facility has been the sole Bard facility from the beginning that has
26 manufactured IVC filters. Bard does maintain a number of other manufacturing facilities
27 around the world, including by way of example facilities in Monck's Corner, South
28 Carolina; Juarez, Mexico; Kedah, Malaysia; and a number of other locations. None of

1 those facilities—indeed no facility other than the Glens Falls Operation, and to a much
2 lesser extent, Bard's Covington, Georgia facility as described below—has ever been
3 involved with the manufacture of IVC filters. Nor have those other manufacturing
4 facilities been otherwise involved with IVC filters.

5 Virtually all of the development, marketing, sales and manufacturing functions
6 involving the filter product line have taken place at the BPV and Glens Falls facilities.
7 However, two additional facilities have some tangential involvement with filters. There
8 are three discrete functions that occur at Bard's Covington, Georgia facility. First, the
9 filters are shipped to that facility after production for the final step in the manufacturing
10 process, sterilization. Second, the Covington office houses Bard's MS&S center, which is
11 a "hot line" that fields inquiries from physicians, patients, and others about the companies'
12 products. Bard notes that a very small number of employees at Covington are engaged in
13 those two functions. Bard also notes that the company has historically produced in
14 litigation records concerning calls fielded by MS&S regarding filters. Finally, the
15 Covington facility is the Global Distribution Center for many of Bard's products,
16 including IVC filters.

17 The other facility having some tangential involvement with filters is the company's
18 corporate headquarters in Murray Hill, New Jersey. Various divisional departments at
19 BPV in Tempe report to their functional counterparts at the corporate level in Murray Hill,
20 principally in the areas of quality assurance, regulatory affairs, and medical affairs.
21 However, the vast majority of employees at Murray Hill have no involvement with filters.

22 As previously noted, Bard has a number of other divisions that handle other
23 product lines. For example, Davol Inc.—located in Warwick, Rhode Island—develops
24 and sells surgical specialty products, including products used in hernia repair, breast
25 reconstruction, and biosurgery. Bard Access Systems, Inc., located in Salt Lake City,
26 Utah, develops access products—such as ports, catheters, and related technologies—that
27 are inserted into the vasculature and used to deliver infusion therapies, such as
28 medications, fluids, and nourishment products to patients. Bard Medical Division focuses

on urological products, such as drainage devices, continence therapies, and brachytherapy treatments. A comprehensive U.S. product catalog can be found at <https://productcatalog.crbard.com/GUI/HeadNavigateDisplay.aspx>. That catalog sets forth a comprehensive listing of the products manufactured by each division of Bard.

In sum, Bard has worldwide operations and facilities that develop and sell a wide array of medical technologies. Only two of those operations, however, have had extensive involvement with Bard's IVC filters: BPV and the Glens Falls Operation. That has been true since Bard's initial commercial introduction of its retrievable IVC filters in 2003. Other than the limited role that Bard's IBC's have had, as described above, there are only two other Bard facilities—Covington and Murray Hill—which have had involvement with filters. The remaining divisions and facilities of Bard are not involved with inferior vena cava filters.

INTERROGATORY NUMBER 2:

Provide a reasonably detailed description of the kinds of information defense counsel obtained from Bard witnesses interviewed as part of Defendants' document and ESI collection efforts in 2005 and 2006; a reasonably detailed description of update efforts Defendants have undertaken with respect to those custodians; reasonably detailed information regarding steps Defendants have taken to locate and produce relevant information from their shared document management system, including QUMAS and Master Control.

RESPONSE:

2005 Document Collection

Bard's initial document collection efforts regarding Bard IVC filters began in the Fall of 2005. At the time, Bard had three pending lawsuits, and the focus of the collection primarily related to the Recovery® and G2® Filters. (By the Fall of 2005, Bard had stopped selling the Recovery® Filter and had begun selling the G2® Filter.) As part of this initial document collection effort, attorneys at Nelson Mullins Riley & Scarborough LLP ("Nelson Mullins") interviewed over 90 employees at the following locations:

- 1 • Bard Peripheral Vascular, Inc. (BPV) in Tempe, Arizona -- the Bard subsidiary
2 primarily responsible for the design, development, marketing, and post-market
3 surveillance of Bard's IVC filters. The document collection at BPV occurred on
4 three different occasions – November 1 to November 3, 2005, November 16 to
5 November 17, 2005, and on December 7, 2005.
- 6 • Bard manufacturing facility in Glens Falls, New York -- the Bard facility
7 responsible for the manufacture of Bard's IVC filters. The document collection at
8 Glens Falls occurred from November 30 to December 1, 2005.
- 9 • Bard corporate headquarters in Murray Hill, New Jersey. The document collection
10 at Murray Hill occurred on January 3 to January 4, 2005.
- 11 • Bard's facility in Covington, Georgia which performs sterilization of the filter
12 products and out of which Medical Services & Support (MS&S) is operated. The
13 document collection at Covington occurred on December 12, 2005.

14 These expansive document collection efforts at these facilities included collection of
15 both electronically-stored information ("ESI") and hard copy documents. A list of
16 custodians who were interviewed and from whom data was collected is included in the
17 chart attached as Exh. A.

18 The 90+ employees who were interviewed for these collection efforts included
19 individuals from research and development, quality assurance, human resources,
20 regulatory and clinical affairs, marketing, sales, manufacturing, accounting, and design, as
21 well as from corporate and executive-level employees. These employees were identified
22 before the collection efforts as individuals who may have information or materials relating
23 to Bard's IVC filters.

24 Attorneys from Nelson Mullins interviewed each Bard employee separately. During
25 these interviews, attorneys from Nelson Mullins asked each employee to identify with
26 specificity all conceivable sources and locations of materials that could relate to the
27 Recovery® or G2® Filters. The employees were specifically asked to identify sources
28 and locations of information, such as hard copy documents, emails, electronic files on

1 their computers, personal network drives, shared network drives, and unique loose
2 electronic media they had which contained Bard IVC filter materials. In addition, to the
3 extent there were documents or ESI pertaining to Bard's IVC filters created by employees
4 who were no longer at Bard at the time of the document collection, attorneys from Nelson
5 Mullins collected those documents as well. Finally, in some circumstances, ESI from
6 former employees had been moved to the computers of their successors, and, thus,
7 relevant information for those former employees was collected when data on the
8 computers of the successor-employees was collected.

9 The general approach to these collection efforts was that if an employee identified
10 documents or electronic files on his or her computer, whether those files were emails,
11 locally archived emails, personal network share files, or files on their desktop or hard
12 drive, the identified information was copied and downloaded to an external hard drive; if
13 the employee identified a source of information with electronic files on his or her
14 computer that he or she was unsure as to whether those files contained relevant
15 information about Bard's IVC filters, those files were downloaded and copied as well.
16 Moreover, while the general approach was to collect hard copy documents identified by
17 custodians that related to the Recovery® or G2® Filters, there were limited instances
18 where such documents or materials were not collected. For example, specific purchase
19 orders and device history and manufacturing records for specific filter lots were not
20 collected, with the knowledge that those documents would be preserved and that the
21 materials would be produced in individual cases, as relevant. To the extent that any
22 identified employee was not in the office during the collection efforts, Nelson Mullins'
23 attorneys worked with Bard's IT department to collect materials from those employees
24 after interviewing the employee by telephone.

25 As part of the employee interviews, the following drives were also identified as
26 having Bard IVC filter-related materials, and they were collected and downloaded to the
27 hard drives in their entirety:

- 28 1) Market shared drive

- 2) Clinical shared drive
- 3) Regulatory shared drive
- 4) Filter shared drive

In total, approximately 185 gigabytes of data was collected and preserved from the 2005/2006 collection.

Given that most of the hard-copy documents that needed to be collected were at BPV, Nelson Mullins retained an outside copy service to bring copiers on site to copy hard copy documents collected from individual employees and documents that were collected in centrally-maintained areas, such as the design history files, fact books, marketing materials, regulatory submissions, and various complaint files.

Post-2005/2006 Document Collection

In 2010 and 2011, after negotiating with counsel representing several plaintiffs with actions pending in Arizona state court and elsewhere, Bard agreed to an ESI protocol for a “second” collection of ESI. As part of this second collection, 24 potential custodians were identified, including “refresh” collections of approximately 14 employees and initial collections from 10 newly-identified employees (many of whom were not hired by Bard until after the initial 2005 collection). Electronic data collected from these individuals included user-created data local to that custodian's desktop/laptop, emails including locally-archived PSTs, and personal network shares. A list of custodians from the 2010/2011 collection is included in the chart attached as Exh. B.

In 2012 and 2013, as part of the *Phillips v. C. R. Bard, Inc.* case formerly pending in the United States District Court for the District of Nevada, the parties extensively briefed and litigated ESI issues. In 2013, in accordance with an order issued by the court in *Phillips*, Bard searched for ESI from 20 “priority” custodians selected by the plaintiff. The electronic data collected from those individuals included all available user-created data local to that custodian's desktop/laptop, emails including locally-archived PSTs, and personal network shares. A list of custodians from the 2012/2013 collection is included in the chart attached as Exh. B.

1 Additionally, over the years, including both before and after the production arising
 2 from the *Phillips* case, Bard has collected and produced extensive materials in response to
 3 expansive discovery requests and document requests included in deposition notices for
 4 filter cases throughout the country. Those materials include “core” materials for each of
 5 its retrievable IVC filters (except Denali®), including the Recovery®, G2®, G2®
 6 Express/G2®X, Eclipse® and Meridian®, such as the following:

- 7 • Design History Files and/or Fact Books
- 8 • Representative marketing materials
- 9 • Representative training materials
- 10 • Regulatory submissions and correspondence
- 11 • Risks analysis documents
- 12 • Complaint trending documents
- 13 • Post-market surveillance documents
- 14 • Complaints from its Trackwise database

15 While Bard has not formally updated collections from the aforementioned shared drives
 16 on a wholesale basis, Bard has continued to collect materials and specific documents
 17 responsive to discovery requests from those and other shared drives. For example, in
 18 response to discovery propounded by plaintiffs in the Bard IVC filter litigation, Bard has
 19 collected and produced voluminous non-IVC filter specific documentation, such as
 20 corporate and divisional policies, procedures, and work instructions relating to complaint
 21 handling, complaint trending, quality, post-market surveillance, new product acquisition,
 22 product design, labeling, manufacturing, and other activities. Other non-IVC filter specific
 23 documents produced by Bard include organizational charts, physician consulting
 24 agreements, and document retention policies.

25 Since 2005, Bard estimates that it has collected and preserved over 2500 gigabytes
 26 of electronically stored information.

Collection from Document Management Systems – QUMAS/Master Control

In 2005, Bard’s document management system for “controlled” documents was called “QUMAS.” During the 2005/2006 document collection, Bard searched and downloaded documents from the QUMAS database using keyword terms “filter” and “recovery.” Starting in or around 2010, Bard began transitioning to a new document management system known as “Master Control.”

While Bard has not performed an updated formal collection of QUMAS since 2005/2006 and has not done a formal collection of the Master Control database, numerous documents have been collected from those databases in response to various discovery requests received by Bard over the years. Moreover, many of the Bard IVC filter-related documents on those systems are duplicative of documents on shared drives. Given the manner in which they were collected, documents collected from the QUMAS and Master Control databases were treated as “hard copy” documents for the purpose of productions.

Bard has also collected and produced in Excel spreadsheet form information from its MS&S database, which has information relating to communications Bard has received relating to the Recovery®, G2®, G2® Express, G2®X, Eclipse® and Meridian® Filters. The last collection from the MS&S database was in the Fall of 2012.

Finally, Bard has collected and produced complaint files from its Easytrack and Trackwise adverse event databases through mid-December 2015 relating to the Recovery®, G2®, G2® Express/G2®X, Eclipse®, Meridian®, and Denali® Filters. Those complaint files include all failure modes and complaints regardless of whether they were MDR-reportable.

INTERROGATORY NUMBER 3:

Identify all combinations of keyword search terms used by Defendants when searching for ESI, including instructions with these combinations of search terms.

RESPONSE:

Bard has used an extensive number of keyword search terms that were negotiated with opposing counsel throughout the Bard IVC filter litigation to search its ESI.

In 2010/2011, after negotiating with counsel representing several plaintiffs with actions pending in Arizona state court, Bard used the following 27 negotiated, broad keyword search terms to search its ESI:

1. filter*
2. recovery
3. "Simon Nitinol"
4. G1A
5. G1*
6. G-1*
7. G2®
8. G2®X
9. G2 Express
10. Eclipse
11. RF
12. RNF
13. SNF
14. "vena cava"
15. IVC, fracture*
16. migrat*
17. tilt*
18. perforat*
19. detach* AND (limb or strut)
20. electropolish*
21. electro-polish*
22. EVEREST
23. deep venous thrombosis
24. DVT
25. embol*
26. Nitinol
27. Recovery

1 These terms were used to search individual custodian ESI as well as the Market, Clinical,
2 Regulatory, and Filter shared drives.

3 In subsequent litigation involving members of the PLC—*Phillips v. C. R. Bard,*
4 *Inc. et al.*, Case No. 3:12-cv-003344, United States District Court for the District of
5 Nevada—the parties and counsel (including members of the PLC Ramon Lopez, Troy
6 Brenes, and Julia Reed Zaic) extensively briefed and argued ESI issues. In 2013, in
7 accordance with an order issued by the court in *Phillips*, the following search terms (in
8 addition to the above 27 search terms) were used to search the ESI of the original
9 custodians (i.e., custodians from whom Bard collected and produced ESI in 2005/2006
10 and 2010/2011) as well as the new “priority” custodians:

- 12 28. Tetra
- 13 29. G3
- 14 30. Platinum
- 15 31. Meridian
- 16 32. Denali
- 17 33. Saturn
- 18 34. Silver
- 19 35. Vail
- 20 36. Venus
- 21 37. Jupiter

22 These 10 additional search terms have been used to search all individual custodians whose
23 ESI has been produced, including custodians whose ESI had been produced before
24 *Phillips*, but these new search terms were not used to search the shared drives.

25 **INTERROGATORY NUMBER 4:**

26 **Identify any testing Defendants have done to determine whether their searches**
27 **for ESI have been over-inclusive or under-inclusive.**

28 **RESPONSE:**

The keyword terms Bard used to search its ESI were negotiated with different
plaintiffs’ counsel, including members of the plaintiffs’ leadership committee. The two
attached reports by Business Intelligence Associates, Inc. (BIA)—Bard’s e-discovery

1 provider—from the *Phillips v. C. R. Bard, Inc.* et al, Case No. 3:12-cv-00344-RCJ-WGC
2 (D. Nev.) case outlines the extent of testing that Bard – through BIA—conducted to assess
3 whether keyword terms were adequate or were over- or under-inclusive. *See* Exhs. C & D.
4 These reports were prepared in response to the Court’s orders in *Phillips* during the
5 timeframe that ESI issues were being litigated.

6 As noted in the May 2013 BIA Report (attached as Exh. C), the plaintiff in *Phillips*
7 sought additional discovery and specifically requested that Bard (i) apply new search
8 terms to the Original Custodians, and (ii) conduct discovery on additional “priority”
9 custodians using both the Original Search Terms and a list of newly-proposed terms.

10 BIA then analyzed the effectiveness of the various search terms and proposals of
11 the parties to assess whether (1) a particular term may have had an abnormally high
12 number of hits for a given custodian or (2) which terms were abnormally high compared
13 with other terms. BIA then used the results of that analysis to sample a random selection
14 of documents that hit on specific custodians and/or terms to formulate and test theories of
15 how to reduce the number of False Hits (e.g., a document that is identified through the use
16 of search terms that is clearly non-responsive to the issues in this matter).

17 As part of that analysis, and as outlined in its report, BIA made seven proposals to
18 reduce the overall document count, primarily by reducing the number of custodians or
19 keywords, or a combination of the two. Thereafter, as noted in its subsequent report
20 (attached as Exh. D), BIA then conducted a statistical sampling of documents with respect
21 to Proposals 2 through 6 to determine the responsive and nonresponsive percentage of
22 documents that would be eliminated if those proposals were followed.

23 Other than the attached proposals, there has been no other testing of the
24 aforementioned previously negotiated and agreed-upon keyword search terms. There also
25 have been no computer-assisted review or computer algorithms used.
26
27
28

INTERROGATORY NUMBER 5:

Identify employees who were involved with the Eclipse®, Meridian®, and Denali® Filters and whose documents and ESI have not yet been produced.

RESPONSE:

Regarding the Eclipse®, Meridian®, and Denali® Filters (collectively, the “later-generation filters”), Bard notes that there have been a large number of employees over a number of the years who have had varying roles involving those filters. As a consequence, it is difficult—if not impossible—for Bard to identify every single individual who, at any anytime, has had a role relating to any of those filters. However, in responding to this interrogatory, Bard has made a good faith effort to identify the principal individuals who were involved with each later-generation filter and also individuals who were more peripherally involved in those filters. Those individuals are set forth below.

1) Bard Employees Who Had a Principal Role with the Eclipse®, Meridian®, and/or Denali® Filters and Whose ESI Has Previously Been Searched¹

Name	Dept	Position or Title (Past and/or Present)	Eclipse	Meridian	Denali	ESI Produced (Y/N) - See attached chart
Bret Baird	Marketing	Franchise Manager-Filter	X			Y
Ed Fitzpatrick	Mfg-GFO	GFO Engineer Mgr	X	X	X	Y
Kevin Bovee	Mfg-GFO	Director Quality Assurance	X	X	X	Y
Jon Conaway	Quality	Quality Engineer	X	X	X	Y

¹ An “X” in red signifies that the individual had a principal role with the specific filter designated.

Name	Dept	Position or Title (Past and/or Present)	Eclipse	Meridian	Denali	ESI Produced (Y/N) - See attached chart
		Director				
Chad Modra	Quality	VP Quality	X	X	X	Y
John Van Vleet	Regulatory	VP Regulatory & Clinical Affairs	X	X	X	Y
Heather Harmison	R&D	Principal Engineer Project Leader-Eclipse®	X	X	X	Y
Mike Randall	R&D	Associate Director of R&D	X	X	X	Y
Andre Chandusko	R&D	Staff Engineer			X	Y
Rob Carr	R&D	Sr. Director of R&D			X	Y
Tracey Estrada	R&D	R&D Project Manager Initial Project Lead Meridian®		X		Y
Bill: Altonaga	Corporate	Medical Director	X	X	X	Y

2) **Bard Employees Who Had a Principal Role with the Eclipse®, Meridian®, and/or Denali® Filters and Whose ESI has NOT Been Previously Searched and Produced**

Name	Dept	Position or Title (Past and/or Present)	Eclipse	Meridian	Denali	ESI (Y/N) See chart	Produced attached
Ryan Melloy	Clinical	Project Manager-Clinical Study			X	N	
Kim Romney	Marketing	Product Manger		X	X	N	
Alicia Burns	Marketing	Product Manger			X	N	
Joni Creal	Regulatory	Regulatory Affairs Associate	X	X	X	N	
Brian Boyle	R&D	R&D Engineer II Co-Project Leader-Eclipse®	X	X		N	
Matt Casiraro	R&D	Senior R&D Engineer Project Lead Meridian®	X	X		N	
Angela Crall	R&D	Program Manager Project Team Leader Denali®		X	X	N	
Joseph Blessan	R&D	R&D Engineer II			X	N	

3) **Bard Employees Who Had a Lesser Role with Later-Generation Filters and the Status of Their ESI**

Name	Dept	Position or Title (Past and/or Present)	Eclipse	Meridian	Denali	ESI Produced (Y/N) See attached chart
John Reviere	Clinical	Director of Clinical Affairs, BPV			X	N
Lissa Garcia	Marketing	Marketing Manager		X		Y
Jeffrey Pellicio	Marketing	Associate Product Mgr	X	X		N
Bill Little	Marketing	VP Global Marketing	X	X	X	Y
Frank Madia	Mfg	GFO Engineer	X	X	X	Y
Pam Welch	Mfg	GFO - Quality Engineer	X	X	X	Y
Carol Felt	Mfg	GFO Engineer	X	X	X	Y
Tom Ferari	Mfg	Engineer GFO - Consultant	X	X		Y
Mark Walaska	Mfg	Staff VP - Mfg	X	X	X	Y
Mike Slavin	Mfg	Engineer GFO			X	Y
Charlie Benware	Mfg	Engineer GFO		X	X	Y
Bruce MacMore	Mfg	Design Transfer	X	X	X	Y
Brian Hudson	Quality	Senior Risk Mgr - Field Assurance	X			Y
Natalie Wong	Quality	Quality Engineer Manager	X			Y
Greg Springer	Quality	Quality Engineer		X		N
Gin Schulz	Quality	VP Quality	X	X		Y
Scott Neal	Quality	Director Quality Eng	X	X	X	Y
Tim Williams	Regulatory	Director of Regulatory Affairs	X	X	X	N

Name	Dept	Position or Title (Past and/or Present)	Eclipse	Meridian	Denali	ESI Produced (Y/N) See attached chart
Laurie Sang	Regulatory	Regulatory Affairs Associate			X	N
Abithal Raji-Kubba	R&D	R&D VP - Mgmt Board	X	X	X	Y
Micky Graves	R&D	R&D Staff Engineer	X	X	X	Y
Brett Curtice	R&D	Data Verifier	X	X	X	Y
Scott Randall	R&D	Director, R&D	X	X	X	N
Robert Landeryou	R&D	Packaging Engineer	X			N
Brian Doherty	Sales	VP Sales	X	X	X	Y

For additional individuals who may have had a briefer or more tangential role with the later-generation filters, Bard refers the plaintiffs to the documents and ESI it has produced, as they are kept in the ordinary course of business, for the names and identity of other individuals involved with those filters. Bard further refers the plaintiffs to the following design history files and regulatory submissions that Bard has produced to date relating to the Eclipse® and Meridian® Filters:

Beginning Bates	Ending Bates	Description
BPV-17-01-00145634	BPV-17-01-00146922	Eclipse™ Filter Design/Development Files
BPV-17-01-00147731	BPV-17-01-00151046	Meridian™ Filter Design/Development Files
BPV-17-01-00151535	BPV-17-01-00152636	Meridian™ Filter Design/Development Files
BPV-17-01-00193315	BPV-17-01-00193321	Testing documentation and related materials (Eclipse®)
BPV-17-01-00145607	BPV-17-01-00145633	FDA Submissions and Correspondence Files regarding Eclipse™ Filter
BPV-17-01-00147141	BPV-17-01-00147610	FDA Submissions and Correspondence Files regarding Meridian™ Filter

Beginning Bates	Ending Bates	Description
BPV-17-01-00147141	BPV-17-01-00147610	FDA Submissions and Correspondence Files regarding Meridian™ Filter
BPV-17-01-00171669	BPV-17-01-00171881	Various FDA Communications
BPV-17-01-00171679	BPV-17-01-00171817	FDA Submissions and Correspondence Files regarding Eclipse™ Filter
BPV-17-01-00171818	BPV-17-01-00171820	FDA Submissions and Correspondence Files regarding Meridian™ Filter
BPV-17-01-00171821	BPV-17-01-00171881	Various FDA Contact Reports
BPV-17-01-00150192	BPV-17-01-00151045	FDA Submissions and Correspondence Files regarding Meridian™ Filter
BPV-17-01-00148516	BPV-17-01-00148534	FDA Submissions and Correspondence Files regarding Meridian™ Filter
BPV-17-01-00116991	BPV-17-01-00117153	FDA Submissions and Correspondence Files regarding Eclipse™ Filter
BPV-17-01-00171679	BPV-17-01-00171793	FDA Submissions and Correspondence Files regarding Eclipse™ Filter
BPV-17-01-00147141	BPV-17-01-00147592	FDA Submissions and Correspondence Files regarding Meridian™ Filter
BPV-17-01-00150192	BPV-17-01-00151045	FDA Submissions and Correspondence Files regarding Meridian™ Filter
BPV-17-01-00142898	BPV-17-01-00142904	Representative marketing/training: Eclipse™
BPV-17-01-00142907	BPV-17-01-00142915	Representative marketing/training: Eclipse™
BPV-17-01-00144162	BPV-17-01-00144166	Representative marketing/training: Eclipse™
BPV-17-01-00151341	BPV-17-01-00151472	Representative marketing/training: Meridian™
BPVEFILTER-01-00043091	BPVEFILTER-01-00043091	Representative marketing/training: Meridian™
BPVEFILTER-01-00043092	BPVEFILTER-01-00043092	Representative marketing/training: Meridian™
BPV-17-01-00147003	BPV-17-01-00147034	CAPAs (Meridian)
BPV-17-01-00147035	BPV-17-01-00147066	Investigational Report (Meridian)
BPV-17-01-00147067	BPV-17-01-00147069	HHE (Meridian)
BPV-17-01-00147070	BPV-17-01-00147106	Remedial Action Plan (Meridian)
BPV-17-01-00147107	BPV-17-01-00147108	Investigation Initiation Request Form (Meridian)

Beginning Bates	Ending Bates	Description
BPV-17-01- 00147109	BPV-17-01- 00147140	Investigation Report (Meridian)

Bard also refers the plaintiffs to the Trackwise complaint files it has produced.

Lastly, Bard is also working on collecting and producing the design history files, regulatory submissions and related correspondence for the Denali® Filter, and Bard anticipates that it will be able to produce those documents within the next 30 days.

DATED this 10th day of February, 2016.

NELSON MULLINS RILEY & &
SCARBOROUGH LLP

By: s/ Matthew B. Lerner

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the above and foregoing has been served by First Class postage prepaid U.S. Mail and by email on February 26, 2016, to the following:

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EXHIBIT A

Exhibit A (Bard 2005/2006 Interview/Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Name	Department	Interview By / Date	Paper Documents	Electronic Information
Tempe				
John McDermott President	Executive	RBN Interview 11/1/05	Yes Gathered	Yes Gathered
Len Decant VP	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Andrzej Chanduszo Staff Engineer	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Brett Curtice Bariat Senior Engineering Tech	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Charlie Simpson Program Director of Interventional Products	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Dan Almazan Engineer I	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Dave Spilka AME Engineer II	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Deb Bebb Senior Technician	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Heather Harmison Senior Engineer	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Jeff Sourbier Senior Engineer (Packaging)	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Micky Graves Senior Engineer	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Nghia Quach Intern	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Phillip Reyes Intern	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Rob Carr Director of Technology, Acquisition & Integration	Research and Development	RBN Interview 11/1/05	Yes Gathered	Yes Gathered
Robert Lerdahl, Senior Engineer	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Stephanie Klocke Senior Engineer	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Khoi Ta Patent Attorney	Research and Development	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Cindi Walcott Field Assurance	Quality Assurance	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Judy Ludwig Document Control Supvr.	Quality Assurance	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Kellee Jones Admin Assistant	Quality Assurance	RBN Interview 11/1/05	Yes Gathered	Yes Gathered
Jonathan Miller Senior Quality Engineering Tech	Quality Assurance	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Brian Hudson Quality Engineering	Quality Assurance	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Kreshmeh Shahriari Quality Engineering	Quality Assurance	RBN Interview 11/16/05	Yes Gathered	Yes Gathered
Douglas Uelmen Former VP of QA	Quality Assurance	N/A	Yes Gathered	Yes Gathered
Shari Allen Director	Regulatory and Clinical Affairs	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Genevieve Balutowski, Sr. RA Specialist	Regulatory Affairs	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Hande Tufanyazici RA Specialist	Regulatory Affairs	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
LeAnn Hord RA Coordinator	Regulatory Affairs	RBN Interview 11/17/05	Yes Gathered	None
Josh Smale RA Associate	Regulatory Affairs	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Karen Hutchinson Sr. Regulatory Specialist	Regulatory Affairs	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Charis Campbell CA Manager	Clinical Affairs	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Elizabeth Rutter Sr. Clinical Affairs Associate	Clinical Affairs	RBN Interview 11/2/05	Yes Gathered	None

Exhibit A (Bard 2005/2006 Interview/Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Name	Department	Interview By / Date	Paper Documents	Electronic Information
Mary Edwards (former VP of Regulatory Affairs)	Regulatory Affairs	N/A	Yes Gathered	Yes Gathered
Kevin Shifrin VP	Marketing	RBN Interview 11/2/05	Yes Gathered	Yes Gathered
Janet Hudnall Marketing Manager (Filters)	Marketing	RBN Interview 11/1/05	Yes Gathered	Yes Gathered
Kim Sherman Admin Assistant	Marketing	RBN Interview 11/1/05	Yes Gathered	None
Alexa McClure Temp	Marketing	RBN Interview 11/1/05	Yes Gathered	None
Joe DeJohn VP	Vascular Sales	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Mark Kumming Professional Development	Vascular Sales	RBN Interview 11/16/05	Yes Gathered	Yes Gathered
Zona Michelena Admin Assistant	Vascular Sales	RBN Interview 11/3/05	Yes Gathered	Yes Gathered
Mary Minske Exec Assistant	Executive	RBN Interview 11/2/05	None	Yes Gathered
Kristin Muir Admin Assistant	Research and Development	RBN Interview 11/3/05	None	Yes Gathered
Inbal Lapid Engineer I	Research and Development	RBN Interview 11/2/05	None	Yes Gathered
Jim O'Brien Senior Technician	Research and Development	RBN Interview 11/2/05	None	Yes Gathered
Judy Murphy Paralegal	Research and Development	RBN Interview 11/2/05	None	None
Lindsay Jaramillo Engineer I (former employee)	Research and Development	N/A	None	Yes Gathered
Gin Schulz VP	Quality Assurance	RBN Interview 11/2/05	None	None
Brian Brown Field Assurance	Quality Assurance	RBN Interview 11/3/05	None	Yes Gathered
Wendy Hayes Quality Systems Manager	Quality Assurance	RBN Interview 11/3/05	None	Yes Gathered
Kim Gonzales Document Control	Quality Assurance	RBN Interview 11/3/05	None	Yes Gathered
Stephanie Lyke Quality Engineer	Quality Assurance	RBN Interview 11/3/05	None	Yes Gathered
Chris Dunn, Quality Engineering	Quality Assurance	RBN Interview 11/2/05	None	Yes Gathered
Mark Wilson Senior Quality Engineer	Quality Assurance	RBN Interview 11/2/05	None	Yes Gathered
Mike Warren VP	Human Resources	RBN Interview 11/3/05	None	None
Sue Stonecipher Admin Assistant		RBN Interview 11/2/05	None	None
Paula Meyer Sr. Admin Assistant	CA	RBN Interview 11/2/05	None	None
Paco Varella International Marketing Manager	Marketing	RBN Interview 11/2/05	None	Yes Gathered
Mary Nielsen Administrative Assistant	Vascular Sales	RBN Interview 11/3/05	None	Yes Gathered
Mike Byrne Supply Chain Manager	Manufacturing Supply Chain Management (Tempe, AZ)	RBN Interview 11/16/05	None	Yes Gathered
Rhonda Peck Master Scheduler	Manufacturing Supply Chain Management (Tempe, AZ)	RBN Interview 11/16/05	None	Yes Gathered
Bill Krueger VP	Accounting	RBN Interview 11/3/05	None	Yes Gathered
Glen Falls				
Mark Walaska Vice President	Manufacturing Quality Assurance	RBN Interview 12/1/05 Date	None	Yes Gathered
Jane Quackenbush Document Control Mgr	Manufacturing Quality Assurance	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Jan Osgood Document Control Administrator	Manufacturing Quality Assurance	RBN Interview 11/30/05	None	None
Elaine Barke Facility Compliance Auditor	Manufacturing Quality Assurance	RBN Interview 11/30/05	Yes Gathered	Yes Gathered

Exhibit A (Bard 2005/2006 Interview/Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Name	Department	Interview By / Date	Paper Documents	Electronic Information
Jeanne Gordon Complaint Coordinator	Manufacturing Quality Assurance	RBN Interview 12/1/05	None	Yes Gathered
Tom Dubois Quality Engineering Mgr	Manufacturing Quality Assurance	RBN Interview 11/30/05	None	Yes Gathered
TaShaunda Gamble Quality Engineer	Manufacturing Quality Assurance	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Loran Chapman Quality Engineer	Manufacturing Quality Assurance	RBN Interview 11/30/05	None	Yes Gathered
Marie Bell Planner	Manufacturing Materials Management	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Steve Meyer Planning Supervisor	Manufacturing Materials Management	RBN Interview 11/30/05	None	Yes Gathered
Dave Freeman Buyer	Manufacturing Materials Management	RBN Interview 11/30/05	Yes Gathered	None
Michelle Weller Purchasing Supervisor	Manufacturing Materials Management	RBN Interview 11/30/05	Yes Gathered	None
Tod Edholm Materials Manager	Manufacturing Materials Management	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Mary Burns BPV Section Manager	Manufacturing Operations	RBN Interview via telephone 12/6/05	Yes Gathered	Yes Gathered
Carol Felt Nitinol Filter Team Leader	Manufacturing Operations	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Harvey Collins Staff Engineer	Manufacturing Engineering	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Ed Fitzpatrick Engineering Mgr	Manufacturing Engineering	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Frank Madia Project Engineer	Manufacturing Engineering	RBN Interview 11/30/05	None	Yes Gathered
Charlie Benware Project Engineer	Manufacturing Engineering	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
John Gallagher Senior Project Engineer	Manufacturing Engineering	RBN Interview 11/30/05	None	Yes Gathered
Kathy Czelusniak Senior Project Engineer	Manufacturing Engineering	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Tom Ferari Contract Quality Engineer	Manufacturing Other	RBN Interview 11/30/05	Yes Gathered	Yes Gathered
Kevin Jenks Former Complaint Coordinator	Quality Assurance	RBN Interview 12/1/05	Yes Gathered	None
Rich Elton Staff Chemist	Manufacturing Engineering	RBN Interview 12/1/05	Yes Gathered	Yes Gathered
Murray Hill				
David Ciavarella	Murray Hill Corporate	RBN Interview 1/4/06	Yes Gathered	Yes Gathered
Chris Ganser	Quality	RBN Interview 1/3/06 & 1/4/06	Yes Gathered	Yes Gathered
Brian Barry	Quality	RBN Interview 1/3/06	Yes Gathered	Yes Gathered
John DeFord	V.P. of Science and Technology Murray Hill Corporate	RBN Interview 1/3/06	Yes Gathered	Yes Gathered
Joe Cherry	Murray Hill Corporate	RBN Interview 1/3/06	Yes Gathered	Yes Gathered
Pete Palermo	Murray Hill Corporate	RBN Interview 1/3/06	Yes Gathered	Yes Gathered
John Weiland	Murray Hill Corporate	RBN Interview 1/4/06	Yes Gathered	None
Tim Ring	CEO, Murray Hill Corporate	RBN Interview 1/4/06	Yes Gathered	Yes Gathered
Judy Reinsdorf	General Counsel, Murray Hill Corporate	RBN Interview 1/4/06	Yes Gathered	Yes Gathered
Donna Passero	V.P. of Science & Technology Murray Hill Corporate	RBN Interview 1/4/06	Yes Gathered	Yes Gathered
Kurt Francis	Murray Hill Corporate	RBN Interview 1/3/06	Yes Gathered	None
Erick Shick	Vice President of Investor Relations Murray Hill Corporate	RBN Interview 1/3/06	Yes Gathered	None
Nadia Adler	Murray Hill Corporate	RBN Interview 1/4/06	Yes Gathered	None
Covington				
Katy Pullen Field Assurance Coordinator	Quality Assurance	RBN Interview 12/12/2005	None	None
Cindy Luttrell QA Supervisor	Quality Assurance	RBN Interview 12/12/2005	Yes Gathered	None
Deborah Griffith Medical Services and Support	Quality Assurance	RBN Interview 12/12/2005	Yes Gathered	None

EXHIBIT B

Exhibit B (Bard ESI Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Custodian	Data Collected (MB)	2005/2006 Collection	2010/2011 Collection	2013 Priority Custodian	Produced
Allen, Shari	1471.182617	Yes			Yes
Almazan, Dan	23994.59277	Yes			Yes
Altonaga, Bill	49345.74805			Yes	Yes
Ament, Mori	188.49414		Yes		
Baird, Bret	29628.0459		Yes		Yes
Ballou, Angie	226.282226		Yes		
Balutowski, Genevieve	95836.33203	Yes			Yes
Barker, Elaine	99.316406	Yes	Yes		Yes
Barry, Brian	296.447265	Yes			Yes
Bartholomew, Jean	309.649414		Yes		
Battease, Brian	193.011718		Yes		
Beasley, Jim	87703.98242		Yes		Yes
Bebb, Deb	1257.557617	Yes	Yes		Yes
Bell, Marie	270.601562	Yes	Yes		Yes
Benware, Charlie	763.105468	Yes	Yes		Yes
Bliss, Richard	1298.143554			Yes	Yes
Bovee, Kevin	385.097656		Yes		
Bradbury, Matt	493.784179		Yes		
Brown, Brian	6110.166992	Yes			
Brown, Charlie	12086.25		Yes		Yes
Buckley, John	212.980468		Yes		
Burns, Mary	426.607421	Yes	Yes		
Busenbark, Regina	223.225585		Yes		
Byrne, Mike	871.876953	Yes			Yes
Campbell, Charis	15143.27734	Yes			Yes
Carr, Robert	51932.28516	Yes	Yes		Yes
Chanduszko, Andre	21988.04199	Yes	Yes		Yes
Chapman, Gary	159.391601		Yes		
Chapman, Loran	47.194335	Yes			Yes
Chavez, Debora	232.364257		Yes		
Cherry, Joe	2067.057617	Yes			Yes
Chunko, Kerry	108.405273	Yes			Yes

Exhibit B (Bard ESI Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Custodian	Data Collected (MB)	2005/2006 Collection	2010/2011 Collection	2013 Priority Custodian	Produced
Ciavarella, David	16579.16699	Yes	Yes		Yes
Cieply, Joe	185.580078		Yes		
Collins, Greg	184.627929		Yes		
Collins, Harvey	36.996093	Yes			Yes
Conaway, John	22555.44824		Yes		Yes
Cramer, Mike	118.689453		Yes		
Croci, Michael	207.929687		Yes		
Curtice, Brett	400.442382	Yes	Yes		Yes
Czelusniak, Kathy	200.11621	Yes	Yes		Yes
Decant, Len	11741.48926	Yes			Yes
DeFord, John	181904.0225	Yes	Yes	Yes	Yes
DeJohn, Joe	608.490234	Yes			Yes
Doherty, Brian	57563.21191		Yes		Yes
Dolch, Gary	2710.551757			Yes	Yes
DuBois, Tom	419.254882	Yes	Yes		Yes
Duensing, Melinda	581.449218		Yes		
Dunn, Chris	67292.72754	Yes			Yes
Edholm, Tom	610.18457	Yes	Yes		Yes
Edwards, Mary	12208.0498	Yes		Yes	Yes
Elton, Rich	245.708007	Yes	Yes		Yes
Estrada, Tracy	20527.99023		Yes		Yes
Felt, Carol	178.583007	Yes	Yes		Yes
Ferari, Tom	460.448242	Yes	Yes		Yes
Ferrin, Mandy	89.551757			Yes	Yes
Fischer, Kurt	495.149414		Yes		
Fitzpatrick, Ed	4235.634765	Yes	Yes		Yes
Freeman, Dave	3259.131835		Yes		
Frowsing, Nathan	115.639648		Yes		
Gaede, Jason	507.566406		Yes		
Gallagher, John	443.605468	Yes	Yes		Yes
Gamble, Tashunda	179.346679	Yes			Yes
Ganser, Christopher	25226.39746	Yes	Yes		Yes

Exhibit B (Bard ESI Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Custodian	Data Collected (MB)	2005/2006 Collection	2010/2011 Collection	2013 Priority Custodian	Produced
Garcia, Jose	5947.986328			Yes	Yes
Garcia, Lissa	329.149414		Yes		
Glass, Holly	531.034179			Yes	Yes
Gonzalez, Kim	2889.221679	Yes	Yes		Yes
Gordon, George	174.602539		Yes		
Gordon, Jeanne	604.53125	Yes			Yes
Graves, Micky	3704.121093	Yes	Yes		Yes
Harmison, Heather	15150.99805	Yes	Yes		Yes
Harrison, Dicey	254.044921		Yes		
Hayes, Wendy	2006.128906	Yes			Yes
Hickok, Chris	320.688476		Yes		
Howard, James	14301.08887		Yes		Yes
Hudnall, Janet	67657.24121	Yes			Yes
Hudson, Brian	102164.3057	Yes	Yes		Yes
Hughes, Scott	310.64746		Yes		
Hutchinson, Karen	2561.92871	Yes			
Jackson, Kevin M	199.242187		Yes		
Jacobsen, Walter	229.67871		Yes		
Jaramillo, Lindsay	2019.813476	Yes			Yes
Jenks, Kevin	71.548828		Yes		
Johnson, Michelle	30165.74805			Yes	Yes
Jones, Kellee	30681.15137	Yes			Yes
Keba, Larry	180.957031		Yes		
Kennison, Doug	142.378906		Yes		
Kerns, Sandy	258.46582		Yes		
Klocke, Stephanie	79604.38086	Yes	Yes		Yes
Kosta, Anisa	323.817382		Yes		
Kowalczyk, Paul	39091.58398			Yes	Yes
Krothapalli, Deep	351.988281		Yes		
Krueger, Bill	60670.85352	Yes	Yes		Yes
Kumming, Mark	220.131835	Yes			Yes
Lapid, Inbal	49112.64648	Yes			Yes

Exhibit B (Bard ESI Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Custodian	Data Collected (MB)	2005/2006 Collection	2010/2011 Collection	2013 Priority Custodian	Produced
Lehmann, John	4241.315429			Yes	Yes
Lerdahl, Robert	302.273437	Yes	Yes		
Linehan, Anne	231.166992		Yes		
Little, Bill	477.422851		Yes		
Little, Peg	168.65625		Yes		
Ludwig, Judith	436.509765	Yes	Yes		Yes
Lyke, Stephanie	262.132812	Yes			Yes
MacDonald, Patrick	176.749023		Yes		
MacMore, Bruce	263.495117		Yes		
Madia, Frank	791.665039	Yes	Yes		Yes
McDermott, John	1319.977539	Yes			Yes
Meyer, Paula	269.755859		Yes		
Meyer, Steve	1142.130859	Yes			Yes
Michelena, Zona	640.958984	Yes			Yes
Micich, Dave	300.701171		Yes		
Miller, Joe	103.163085		Yes		
Miller, Jonathan	212.886718	Yes			Yes
Minske, Mary	3654.96582	Yes	Yes		Yes
Modra, Chad	169521.2549			Yes	Yes
Muir, Kristin	340.200195	Yes			Yes
Mukherjee, Avijit	95.975585			Yes	Yes
Neal, Scott	16480.10059		Yes		Yes
Nielsen, Mary	10404.42773	Yes	Yes		Yes
O'Brien, Bob	207.36621		Yes		
O'Brien, Jim	542.853515	Yes	Yes		Yes
Orms, Dan	343.615234		Yes		
Orsay, Thomas	165.452148		Yes		
Osgood, Jan	275.78125		Yes		
Palermo, Pete	1683.665039	Yes	Yes		Yes
Passero, Donna	54.274414	Yes			Yes
Peck, Rhonda	274.224609	Yes			Yes
Portillo, Jesse	46.836914		Yes		

Exhibit B (Bard ESI Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Custodian	Data Collected (MB)	2005/2006 Collection	2010/2011 Collection	2013 Priority Custodian	Produced
Quach, Nghia	6.677734	Yes			
Raji-Kubba, Abtihal	24691.0957		Yes	Yes	Yes
Randall, Mike	101253.2539		Yes		Yes
Rauch, David	41.743164			Yes	Yes
Reinsdorf, Judy	7.39746	Yes			Yes
Reyes, Phillip	249.420898	Yes			Yes
Ring, Tim	55414.18652	Yes	Yes	Yes	Yes
Salzmann, Dennis	48072.41797		Yes		Yes
Sanford, Tony	304.999023		Yes		
Scherer, Bob	270.490234		Yes		
Schlichenmaier, Matt	167.732421		Yes		
Schulz, Gin	77456.00195		Yes		Yes
Seelig, Michael	264.951171		Yes		
Shahriari, Kreshmeh	269.765625	Yes			Yes
Shamji, Imtiaz	470.84082		Yes		
Sherman, Kim	0.041015				
Shick, Eric	482.427734		Yes		Yes
Shifrin, Kevin	331.995117	Yes			Yes
Simpson, Charlie	19916.29297	Yes			Yes
Slavin, Mike	211.555664		Yes		
Smale, Joshua	82751.93066	Yes	Yes		Yes
Smithson, Robin	478.46289		Yes		
Sourbier, Jeff	696.58496	Yes			
Spilka, Dave	5895.37207	Yes			Yes
Stewart, Travis	62.099609		Yes		
Stonecipher, Sue	152.686523		Yes		
Streets, Doug	120.729492		Yes		
Sullivan, Jack	381.644531		Yes		
Ta, Khoi	1816.589843	Yes			Yes
Tessmer, Alex	30588.17285			Yes	Yes
Thompson, Jeanne	172.454101		Yes		
Tinsley, Mark	370.814453		Yes		

Exhibit B (Bard ESI Collection Chart)

In Re: Bard IVC Filters Products Liability Litigation

Custodian	Data Collected (MB)	2005/2006 Collection	2010/2011 Collection	2013 Priority Custodian	Produced
Tufanyazici, Hande	231.073242	Yes			Yes
Tuten, Jeremy	60.620117		Yes		
Uelmen, Doug	4713.383789	Yes			Yes
Van Vleet, John	211316.8389		Yes		
Varella, Paco	360.030273	Yes			
Walaska, Mark	6867.15039	Yes	Yes		
Walcott, Cindi	14373.9834	Yes	Yes		Yes
Warren, Mike	5886.966796		Yes		
Waugh, Cullen	169.36621		Yes		
Weiland, John	7289.612304		Yes		Yes
Welch, Pamela	280.02246		Yes		
Weller, Michelle	262.529296		Yes		
Whelan, Preston	78.83789		Yes		
Wilson, Mark	877.191406	Yes	Yes		Yes
Wong, Natalie	108899.6465		Yes		Yes
Wright, Jeremy	147.480468		Yes		
Drive-Clinical	6585.802734	Yes			Yes
Drive-FilterDrive	13156.04297	Yes			Yes
Drive-Market	172480.5879	Yes			Yes
Drive-RegulatoryAffairs	17894.42676	Yes			Yes

EXHIBIT C



Phillips v. C.R. Bard, Inc. et al

(3:12-cv-00344-RCS-WGC)

Proposed Discovery Protocol Analysis Report

Summary

Through a in-depth analysis of the various proposed search criteria as detailed below, refined search criteria has been created that we believe appropriately limits Plaintiff's proposed search criteria, results in the elimination of a large percentage of non-responsive documents that were "false hits", focuses certain groups of custodians where appropriate, and substantially reduces the burden to Bard in this matter. As described in detail, the proposed new search criteria results in reducing the number of documents to review from 199,608¹ to 71,212, with an associated cost estimate of \$237,000².

Background

Prior to this action, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), conducted document discovery processes in related actions that resulted in 297,783 documents and 2,057,570 pages being produced from 82 custodians (the "Original Bard Custodians"). In that effort, Bard used a negotiated list of 27 search terms (the "Original Bard Search Terms"). See Appendix A. Copies of those productions have been provided to Plaintiff in this matter.

Plaintiff sought additional discovery from Bard in this matter beyond the documents previously produced. Generally speaking, Plaintiff requested that Bard (i) apply new search terms to the Original Custodians, and (ii) conduct discovery on an additional 75 custodians using both the Original Bard Search Terms and a list of newly proposed terms.³ The parties conducted several meet and confer sessions, but could not agree on the scope of additional discovery.

On March 1, 2013, after hearing both parties' positions, the Court issued an Order which set forth a defined protocol for further discovery. Specifically, the Court stated that Plaintiff could (i) propose a new set of search terms to be used search on the Original Bard Custodians, and (ii) identify up to 20 new "priority" custodians ("Plaintiff's Priority Custodians") whose data would be searched both with the Original Bard Search Terms and Plaintiff's new search terms. The Court also stated that Bard would have the opportunity to object to the additional discovery if the burden was significant.

¹ Bard's original estimate was 181,450 documents, but we noted that 11GB of data had not yet been searched. See *Supplemental Declaration of Brian Schrader in Support Of Bard's Motion For Protective Order Concerning ESI Discovery* at paragraph 5(a) (Dkt. No. 95-2). Searching that remaining 11GB added 18,158 documents to the overall count. Thus, we started this analysis with 199,608 documents.

² This cost estimate was derived using the average cost per document of \$3.33 from the BIA's prior estimated costs.

³ Plaintiff's original list of proposed new custodians and proposed search terms have not been included in this report to prevent confusion, as both were later modified by Plaintiffs, and thus, were not subject to this analysis.



Phillips v. C.R. Bard, Inc. et al

(3:12-cv-00344-RCS-WGC)

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On March 11, 2013, Plaintiff presented its list of proposed new search terms⁴ to Bard. Those search terms consisted of 32 Anchor Terms and 171 Connector Terms (“Plaintiff’s New Search Terms”). See Appendix B. Following an analysis of Plaintiff’s New Search Terms and Plaintiff’s Priority Custodians, Bard objected to Plaintiff’s requests based on the burden it would impose on Bard, namely that the combination of (i) applying the Original Bard Search Terms to Plaintiff’s Priority Custodians, and (ii) applying Plaintiff’s New Search Terms on both the Original Bard Custodians and the Plaintiff’s Priority Custodians, would result in at least 181,450 documents to review at a cost to Bard of approximately \$605,000 (as stated above, the total number after searching the last 11GB rose to 199,608). The parties could not agree on a compromise, and Bard filed for a protective order.

On May 8, 2013, Plaintiff proposed reducing the Anchor Terms in Plaintiff’s New Search Terms from the original 32 Anchor Terms to 10 Anchor Terms (specifically: Tetra, G3, Platinum, Meridian, Denali, Saturn, Silver, Vail, Venus, and Jupiter) (the “Reduced Plaintiff Anchor Terms”). While BIA was not able to test that proposed reduction prior to the hearing, that has been done since the hearing as described below.

During the May 13, 2013 hearing of *Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.’s Motion for Protective Order Concerning ESI Discovery*, the Court directed Bard’s eDiscovery expert Business Intelligence Associates, Inc. (BIA) to conduct an in-depth analysis of the proposed discovery protocols subject to that motion and provide a report by Wednesday, May 22, 2013. BIA’s experts have undertaken that task, and hereby submit this report.

The Detailed Hit Reports & Initial Analysis

To examine the effectiveness of the various search terms, BIA first created detailed hit reports⁵ that would show how each of the various proposed search methods individually performed against each of the custodians.

We created three primary reports to help in this analysis:

1. The **Reduced Plaintiff Anchor Terms – Priority Custodians Detailed Hit Report** in Appendix C shows the number of raw hits using Plaintiff’s reduced 10 Anchor Terms with the 171 Connector Terms as applied to Plaintiff’s Priority Custodians.
2. The **Reduced Plaintiff Anchor Terms – Original Bard Custodians Detailed Hit Report** in Appendix D shows the number of raw hits using Plaintiff’s reduced 10 Anchor Terms with the 171 Connector Terms as applied to the Original Bard Custodians.

⁴ Plaintiff’s New Search Terms consisted of 32 “Anchor” terms and 171 “Connector” terms. The Anchor terms are the primary search terms, and the Connector terms are intended to be used in conjunction with the Anchor terms with the expectation that those Connector terms will help narrow the scope of the Anchor Terms.

⁵ Note that all the reports include a column titled “Family Docs (without hits)”. This column identifies how many documents were pulled into a given custodian’s document collection where the documents themselves do not contain any of the proposed search terms. This function is usually referred to as “with families” and reflects the standard process in eDiscovery whereby an entire related set of documents is pulled in for review if a single member of that document set hits on a search term. For example, if an email that has two attachments hits on a search term, but the two attachments do not hit on a search term, it would result in all three documents (the email plus its two attachments) being identified for review, as any standard review does not split up “family” document sets.

3. The **Original Bard Search Terms – New Priority Custodians Detailed Hit Report** in Appendix E shows the number of raw hits using Bard’s Original Search Terms as applied to Plaintiff’s Priority Custodians.

We also created two additional reports mainly for informational purposes:

1. The **Discarded Plaintiff Anchor Terms – Priority Custodians Detailed Hit Report** in Appendix F shows the number of raw hits using Plaintiff’s discarded 22 Anchor Terms and 171 Connector Terms as applied to Plaintiff’s Priority Custodians.
2. The **Discarded Plaintiff Anchor Terms – Original Bard Custodians Detailed Hit Report** in Appendix G shows the number of raw hits using Plaintiff’s discarded 22 Anchor Terms and 171 Connector Terms as applied to the Original Bard Custodians.

For each of the above reports, we ran the individual searches and created a pivot table (basically a cross-reference chart) that lists the custodians on the left side and the search terms across the top. The result shows which terms result in abnormally high hits for certain custodians (as compared to all other results in the individual report) and overall for all custodians.

We then augmented the reports with a green-yellow-orange-red scale where green represents a relatively low hit count and red represents a relatively high hit count. This scale itself is an objective automatic formula function available in the Microsoft Excel program, and is not the result of any potentially biased subjective analysis.

Initial Analysis of the Detailed Hit Reports

The reports, assisted by the color augmentation, helps make clear where a particular term may be abnormally high for a given custodian and which terms are abnormally high as compared with all other terms. For example, only 11 of the 27 Original Bard Search Terms make up more than 76% of the hits. With respect to Plaintiff’s New Search Terms, 7 of the Anchor Terms make up nearly 88% of the hits.

We also sorted the Custodians in each report by total number of hits so that the custodians were listed in descending order by the number of hits. With respect to the Original Bard Search Terms applied to the Priority Custodians, the top five custodians make up nearly 75% of the total hits. Likewise, with respect to the application of Plaintiff’s New Search Terms against the Original Bard Custodians and Plaintiff’s Priority Custodians, the top 14 custodians make up nearly 75% of the total hits. Three of the top five custodians in the first example are also contained within the top 14 of the second example.

That analysis allowed us to focus our efforts on the search terms and custodians that made up the vast majority of the overall results. The simple reasoning being that it would be most likely those search terms and custodians were resulting in the most significant “False Hits.”⁶

BIA’s experts then used that information to sample random selections of documents that hit on those custodians and/or terms, worked with others on the team who were involved in the various related reviews to formulate and test theories of how to effectively reduce the number of False Hits, and numerous other approaches. Generally speaking, BIA’s experts looked for ways to limit the search

⁶ A “False Hit” for purposes here refers to any document that is identified through the use of search terms that is clearly non-responsive to the issues in this matter.

criteria in a way that could help eliminate the False Hits while not materially impacting the ability of the search criteria to identify potentially responsive documents.

Removal of Custodians and/or Search Terms

The simplest and most effective method for reducing the burden of eDiscovery is to reduce the number of custodians and/or search terms used. Indeed, late last year, the Federal Circuit Advisory Council released a model order for patent litigations that recognized that method, specifically limiting eDiscovery (at least initially) to five custodians and five search terms.

Here we have not recommended the removal of any custodians and/or search terms, as we believe that decision to be a **subjective** one that is better left to counsel. However, counsel and/or the Court can utilize the charts provided in Appendixes C-E to see the general effect removing any particular custodian and/or keyword may have on the overall document count.

Proposed Search Alterations

Using the information in the reports and our initial analysis, BIA's experts examined a number of objective methods for potentially reducing the overall number of documents to be reviewed. Based on our analysis and on Plaintiff's offer to reduce the number of Anchor Terms, we have identified the following as the best **objective** methods to reduce the overall document count. If all of the proposals below are acceptable, the total document count will be reduced from 199,608 to 71,212.

It is important to note that some of the proposals below overlap. For example, in one proposal we recommend using Plaintiff's Connector Terms in conjunction with Bard's Original Search Terms. In another we recommend focusing the searches for the senior executives. It's likely that some documents would be ruled out by each method. This explains why you cannot simply add up the individual reductions listed under each proposal. The overall reduction stated above takes all of the proposed methods below into account.

Proposal #1: Reducing the 32 Anchor Terms to 10 Anchor Terms

Net Impact: Reduces the number of documents to be reviewed by 38,775.

Reasoning: Plaintiff has proposed reducing the number of Anchor Terms from the initially proposed 32 Anchor Terms to 10 Anchor Terms.

Proposal #2: Use Plaintiff's Connector Terms with Bard's Original Search Terms

Net impact: Reduces the documents to be reviewed by 14,824.

Reasoning: Plaintiff has previously proposed limiting their Anchor Terms by using 171 Connector Terms intended to narrow the scope of the primary Anchor Terms. While recognizing that Plaintiff's Connector Terms have a limited impact in reducing the number of documents returned in searches using their previously proposed 32 Anchor Terms, we found that there is benefit to be derived from using those Connectors Terms with Bard's Original Search Terms.

Proposal #3: Better Focused Searches for Senior Executives

Net impact: Reduces the documents to be reviewed by 63,654.

Reasoning: Custodians Tim Ring, John DeFord, Gary Dolch, Bill Altonaga, Richard Bliss, Abtihal Raji-Kubba, and Mary Edwards, all part of Plaintiff's Priority Custodian set, each hold or have held senior positions at Bard. As can be seen from the report at Appendix C & E, all of these custodians are among the highest hit counts. However, given their senior positions and given that custodians Altonaga, Edwards, Bliss, Dorch and Raji-Kubba are each involved in product safety and performance areas rather than sales, marketing or other similar areas, BIA believes it is appropriate to focus the searches of their documents plus the two most senior executives, Ring and DeFord, to terms related to failure modes, thus limiting the number of marketing, sales and other similar documents from review. The total number of documents for this group of seven custodians is 90,213. Documents identified by the various failure modes are 26,559. The terms used to identify these documents include a combination of Plaintiff's Connector Terms as well as specific Bard Original Search Terms. The specific search string used is: *((Embol*, Perforat*, detach*, "Deep venous thrombosis", DVT, fract*, migrat*, Abnormal*, bleed*, buckl*, Dislodg*, Fragment*, hemorrhag*, lacerat*, protru*, puncture*, penetrat*, pierc*) & (Filter or filters or g2 or denali or vail or meridian or tetra or recovery or g1 or g3))*.

Proposal #4: Exclusion of "off-label" related documents

Net Impact: Reduces the documents to be reviewed by 10,841.

Reasoning: Several of the Connector Terms proposed by Plaintiff relate to the issue of off label marketing. It appears that there is not an issue in the matter about off-label use, and thus, it seems appropriate to eliminate these documents from the review process. The total number of documents that will not be reviewed as a result of removing these from the reviewable document group is 10,841. The specific search string used is: "off label" or "off-label".

Proposal #5: Exclusion of competitor product related documents

Net Impact: Reduces the documents to be reviewed by 3,899.

Reasoning: Plaintiffs removed the names of competing products from their original Anchor Terms when they proposed reducing those terms. While that eliminated most of the documents that discuss competing products, it did not remove all. Moreover, based on BIA's experience in reviewing documents for this matter and various related matters, any document that discusses competitive products generally are not critical to the issues in this litigation. The specific search string used is: "opt ease" OR optease OR birdsnest OR "bird's nest" OR celect OR greenfield OR tulip OR trapease.

Proposal #6: Exclusion of non-relevant file types

Net Impact: Reduces the documents to be reviewed by 6,243.

Reasoning: BIA has been able to identify 6,243 files that are pulled into the review only because they are "family members" of a document that hit on search terms, but that are clearly non-responsive and would not require review. Those files are pictures or graphics and other similar file types that are

associated with email signatures and similar issues and can be identified, briefly sampled and eliminated without any need for extensive review.

Proposal #7: Inclusion of “bariatric” related documents

Net Impact: Ensures that 17,196 documents that may be otherwise excluded are specifically included.

Reasoning: Plaintiff appears to have an interest in documents concerning the Recovery Filter® and bariatric patients. To that end, and to ensure that those documents are not excluded by any of the above proposals, we have identified, as have Plaintiffs through certain of their proposed Connector Terms, a series of terms that will permit review of a set of documents on this topic. The total number of documents that will be reviewed as a result of identification of these documents is 17,196. The specific search string used is: "lap band" OR bariatric OR morbid*.

Appendix A

Original Bard Search Terms

1. Filter*
2. "Simon Nitinol"
3. G1A
4. G1*
5. G2
6. G2X
7. G2 Express
8. Eclipse
9. RF
10. RNF
11. SNF
12. "vena cava"
13. IVC
14. Fracture*
15. Migrat*
16. Tilt*
17. Perforat*
18. Detach* and (limb or strut)
19. electropolish
20. Electro-polish
21. EVEREST
22. "Deep venous Thrombosis"
23. DVT
24. Embol*
25. Nitinol
26. Recovery
27. G-1*

Appendix B**Plaintiff's New Search Terms**

<u>32 Anchor Terms</u>	<u>171 Connector Terms</u>			
<i>Focused Terms:</i> 1. Tetra 2. G3 3. Platinum 4. Meridian 5. Denali 6. Saturn 7. Silver 8. Vail 9. Venus 10. Jupiter <i>Discarded Terms:</i> 11. K080668 12. K062887 13. K050558 14. K082305 15. K073090 16. K052578 17. K062887 18. K093659 19. K944353 20. K022236 21. K031328 22. K101431 23. K102511 24. K112497 25. Greenfield 26. celect 27. tulip 28. "Bird's Nest" 29. "Vena Tech" 30. "Opt Ease" 31. "Trapease" 32. "Tight Spline" *Note that the original list also included "Everest", but since that was an Original Bard Search Term, it was not included here.	1. 483 2. 25539 3. "field action" 4. "focus group" 5. "foreign body" 6. "not as intended" 7. "Performance Specification*" 8. "product life cycle" 9. 'customer needs' 10. "Division of Device Marketing Advertising and Communications" 11. "adverse event" 12. "arm length" 13. "as low as reasonably possible" 14. "blood vessel" 15. "Communication plan" 16. "Design History File" 17. "Device Master Record" 18. "enforcement action" 19. "Equity Research" 20. "Fault Tree" 21. "hook diameter" 22. "human factor*" 23. "Instructions for Use" 24. "lap band" 25. "leg span" 26. "life threatening" 27. "medical device Report" 28. "off label" 29. "product development and commercialisation plan" 30. "Product Opportunity Appraisal" 31. "radial force" 32. "root cause" 33. "Safety Communication" 34. "shape memory alloy" 35. "Shelf Life" 36. "system hazard analysis" 37. "use by date" 38. "wire diameter" 39. "Dear Doctor Letter" 40. "Dear Dr. letter"	41. "product Development" 42. "Project Team" 43. "Safety Alert" 44. 510k 45. Abnormal* 46. Aging 47. ALARP 48. anchor* 49. angulation 50. animal 51. autops* 52. bariatric 53. bleed* 54. broken 55. buckl* 56. cardiac 57. caudal 58. caus* 59. caval 60. ceph* 61. clip* 62. clot* 63. Complain* 64. contaminat* 65. corrosion 66. cross* 67. damag* 68. danger* 69. DDPAC 70. death 71. defect* 72. deform* 73. deploy* 74. design* 75. deviat* 76. DFMEA 77. DHF 78. Dislodg* 79. displac* 80. disten* 81. DMR 82. embed* 83. Endoth* 84. evaluat* 85. expire* 86. exten* 87. Extravas* 88. extru* 89. F2129 90. Fail* 91. failure*	92. fatal* 93. fatigue* 94. FDA 95. Feasibility 96. FMEA 97. FMECA 98. Fragment* 99. FTA 100. harm* 101. Hazard* 102. hemorrhag* 103. HF&E 104. HHA 105. HHE 106. histopathological 107. IFU 108. implant* 109. incident* 110. inclusion* 111. Inflamm* 112. injur* 113. Integrity 114. investigat* 115. kink* 116. lacerat* 117. lap-band 118. Lesion* 119. life-threatening 120. malfunction* 121. malposition* 122. Market* 123. material* 124. MAUDE 125. MDR 126. MHRA 127. misassembl* 128. misdeploy* 129. Missing (w/in 2 of) strut*, or component*, or leg*, or arm*, or part*, or device 130. misuse* 131. morbid* 132. mortalit* 133. movement 134. 'near incident*' 135. nitinol 136. occlu* 137. Off-label 138. organ	139. outcome* 140. pain* 141. PDCP 142. PDP 143. penetrat* 144. Pierc* 145. PLC 146. pressur* 147. problem* 148. Product Specification* 149. protr* 150. puncture* 151. Recall 152. redesign 153. renal 154. Risk 155. SAE 156. safe* 157. separat* 158. sever* 159. Stability 160. Stress* 161. tamponade 162. tenting 163. tip* 164. TPLC 165. twist* 166. Validation 167. valsalva 168. Verification 169. Vigilance 170. warning* 171. worn

Appendix C**Reduced Plaintiff Anchor Terms – Priority Custodians Detailed Hit Report**

This report shows the number of raw hits using Plaintiff's reduced 10 Anchor Terms with the 171 Connector Terms as applied to Plaintiff's Priority Custodians. Note that if a custodian is not included on the report, it is because there were no data or search term hits.

	denali	G3	jupiter	meridian	platinum	saturn	silver	tetra	vail	venus	Family Docs	Grand Total	% Hits by Cust.	
Custodian														
DeFord, John	993	469	34	661	760	93	2,644	16	43	35	5,733	11,481	28.89%	
Ring, Tim	242	114	145	555	457	193	1,333	48	149	218	2,982	6,436	16.20%	
Modra, Chad	338	112	97	833	287	11	995	11	129	50	3,494	6,357	16.00%	
Kowalczyk, Paul	59	105	51	105	264	3	1,002	5	15	30	2,505	4,144	10.43%	
Altonaga, Bill	347	141	44	723	293	4	531	34	84	40	1,253	3,494	8.79%	
Tessmer, Alex	129	64	41	649	247		131	5	61	2	1,462	2,791	7.02%	
Raji-Kubba, AbtihaI	321	115	4	283	192	8	141	2	22	2	474	1,564	3.94%	
Edwards, Mary	2	37	19	42	71	6	132	12	16	4	617	958	2.41%	
Johnson, Michelle	7	6	83	96	23	5	90		91	10	308	719	1.81%	
Bliss, Richard		33		1	2		26		17		506	585	1.47%	
Lehmann, John	1		4	2	37		163	2	1	2	258	470	1.18%	
Dolch, Gary	27	9	4	46	32		82	2	8	2	157	369	0.93%	
Garcia, Jose		14	2	2	141		6	2	1	20	152	340	0.86%	
Glass, Holly			3				7				7	17	0.04%	
Rauch, David				2	1		1				2	6	0.02%	
Ferrin, Mandy							4		1			5	0.01%	
Total	2,466	1,219	531	4,000	2,807	323	7,288	139	638	415	19,910	39,736		
% Hits by Term	12.44%	6.15%	2.68%	20.18%	14.16%	1.63%	36.76%	0.70%	3.22%	2.09%				

Appendix D

Reduced Plaintiff Anchor Terms – Original Bard Custodians Detailed Hit Report

This report shows the number of raw hits using Plaintiff's reduced 10 Anchor Terms with the 171 Connector Terms as applied to the Original Bard Custodians.

Custodian	denali	G3	jupiter	meridian	platinum	saturn	silver	tetra	vail	venus	Family Docs	Grand Total	% Hits by Cust.
Beasley, Jim	175	184	64	82	681	47	960	12	100	10	2,546	4,861	20.14%
Harmison, Heather	1,086	10		745	171		9	2	298		530	2,851	11.81%
Klocke, Stephanie	24	765	14	3	346	2	79	104	9	13	905	2,264	9.38%
Conaway, John	701		1	224	12	3	21		1		507	1,470	6.09%
Estrada, Tracy	173	11		768	42		28	1	7		258	1,288	5.34%
Neal, Scott	35		7	40	66	2	558		7		461	1,176	4.87%
Salzmann, Dennis	1	16	12	5	42	5	536			6	398	1,021	4.23%
Ciavarella, David	52	8	2	4	8		589	2	3		291	959	3.97%
Carr, Robert	52	14	14	14	189	45	156	8	59	5	391	947	3.92%
Hudson, Brian	12	23	18	11	42	5	237	3	20	1	350	722	2.99%
Randall, Mike	198	56		107	119		14	2	34		147	677	2.81%
Wong, Natalie	39	127	25	29	42	1	158	11	16	2	213	663	2.75%
Chandusko, Andre	160	194	2	25	34		9	9	3	5	195	636	2.64%
Baird, Bret	156	7	26	52	85		92		49		155	622	2.58%
Graves, Micky	60	13	5	12	108		49	4	11	5	222	489	2.03%
Schulz, Gin	9	6	15	24	36	1	139	1	4	1	196	432	1.79%
Simpson, Charlie		8	3	2	57	8	76			1	183	338	1.40%
Howard, James		18	1	7	27	1	148		4		107	313	1.30%
Nielsen, Mary		3	12	35	6		107		26		118	307	1.27%
Hudnall, Janet		28	11	3	16	8	22				169	257	1.06%
Balutowski, Genevieve			2		79	1	10			1	97	190	0.79%
Cherry, Joe		6		5	14	11	48				103	187	0.77%
Ganser, Christopher		1	1	1	28	1	99		1		46	178	0.74%
Palermo, Pete		2			25	1	46	4			94	172	0.71%
Uelmen, Doug			1	1	10	2	46		8		93	161	0.67%
Fitzpatrick, Ed	28	2	1	42	32		29		5	1	20	160	0.66%
Walcott, Cindi	1	9	9	3	13		62		3	1	52	153	0.63%
Barry, Brian			3	2	4		59			4	48	120	0.50%
Michelena, Zona							65				24	89	0.37%
Dunn, Chris				1	1		27				36	65	0.27%
Hayes, Wendy					14		7		12		23	56	0.23%
Lapid, Inbal			16		4		11			10		41	0.17%
DuBois, Tom					17		13				4	34	0.14%
DeJohn, Joe							4				25	29	0.12%
Weiland, John				4	5		14				5	28	0.12%
Byrne, Mike			3			1	5				17	26	0.11%
Ta, Khoi			4		1		8				9	22	0.09%
Brown, Brian			1		2		10		1		6	20	0.08%
Campbell, Charis				2			5		4		8	19	0.08%
Shifrin, Kevin							1		1		12	14	0.06%
Jaramillo, Lindsay					6		4				2	12	0.05%
McDermott, John				3	1		2				6	12	0.05%
Chapman, Loran							1		1		5	7	0.03%
Smale, Joshua							3			1	2	6	0.02%
Chunko, Kerry					5							5	0.02%
Madia, Frank					1		1				3	5	0.02%
Benware, Charlie					2		2					4	0.02%
Edholm, Tom					1						3	4	0.02%
Peck, Rhonda							1				3	4	0.02%
Reyes, Phillip			2							1		3	0.01%
Shahriari, Kreshmeh					1						2	3	0.01%
Gallagher, John					2							2	0.01%
Minske, Mary						1					1	2	0.01%
Varella, Paco							2					2	0.01%
Czelusniak, Kathy					1							1	0.00%
Ferari, Tom					1							1	0.00%
Gamble, Tashunda					1							1	0.00%
Ludwig, Judy			1									1	0.00%
Total	2,962	1,511	276	2,256	2,400	146	4,572	163	687	68	9,091	24,132	
% Hits by Term	19.69%	10.05%	1.83%	15.00%	15.96%	0.97%	30.40%	1.08%	4.57%	0.45%			

Appendix E

Original Bard Search Terms – New Priority Custodians Detailed Hit Report

This report shows the number of raw hits using Bard's Original Search Terms as applied to Plaintiff's Priority Custodians.

Custodian	Deford, John	Modra, Chad	Ring, Tim	Altonaga, Bill	Edwards, Mary	Kowalczyk, Paul	Lehmann, John	Tessmer, Alex	Raji-Kubba, Abthai	Garcia, Jose	Dolch, Gary	Johnson, Michelle	Bliss, Richard	Mukherjee, Avijit	Glass, Holly	Ferrin, Mandy	Rauch, David	Total	% of Hits by Term
G1**	404	558	124	410	150	149	20	40	47	14	20	10	69	1	2			2,017	1.06%
Deep Venous Thrombosis	130	111	10	226	32	23	395	17	14	35	5	2	1					966	0.51%
DVT	550	1,374	378	1,656	222	340	95	218	130	81	81	2	117					5,207	2.73%
Eclipse	485	664	175	501	141	83	624	103	60	26	26	8	7					2,885	1.51%
Electrocardiogram*	644	898	390	447	46	78	7	376	200	1	50	10	16					3,166	1.66%
Emboli*	478	210	20	162	22	49		17	81	15	4	3	18					1,080	0.57%
Everest	132	90	57	19	12	8		13	65	2	1	2	3					406	0.21%
Filter*	2,531	2,259	1,114	2,760	1,288	704	1,064	1,017	437	28	106	54	23					13,424	7.04%
Fracture*	795	255	556	194	6	60	61	603	134	9	6	2	1					3,584	1.88%
G1*	5,244	7,203	3,019	2,515	3,487	1,908	2,353	1,885	1,053	692	386	233	160					30,298	15.88%
G1A	2,704	2,457	1,223	2,086	648	481	854	330	453	22	151	14	84					11,534	6.05%
G2	939	362	18	461	178	215	18	131	190	109	47	44	27					3,783	1.98%
G2 Express	402	7	7	41	85	47		3	3	20	18	18	7					696	0.36%
G2X	2,141	639	526	629	114	145	322	371	397	972	145	42	55					10,030	5.26%
N/C	639	287	133	150	256	91	999	261	153	771	15	60	13					2,844	1.49%
limb	287	709	114	256	553	212	999	304	59	9	95	1	100					1,860	0.98%
Migrat*	994	1,115	454	1,243	412	249	999	304	218	115	6	45	13					8,054	4.22%
Natural	1,115	886	328	1,063	916	249	999	304	307	6	165	103	21					5,217	2.73%
Perforat*	1,864	1,714	1,565	2,431	1,254	656	1,184	1,884	397	42	31	112	104					11,473	6.01%
Recovery	2,886	1,503	462	2,239	576	859	293	565	397	386	156	13	104					9,046	5.32%
Rt	1,402	1,771	666	1,321	3,397	682	668	767	220	30	182	166	63					23,793	12.47%
RtF	4,158	3,660	8,296	1,321	559	1,556	1,945	422	340	63	45	47	39					8,585	4.50%
Simon Natural	347	161	65	121	223	12	14	1	16	72	26	9	13					1,086	0.57%
Suit	115	444	57	119	385	288	130	76	24	10	5	22	13					1,695	0.89%
Ttk*	133	412	95	120	697	213	68	290	34	29	6	22	17					2,146	1.12%
Vena Cava	485	372	79	307	124	44	313	113	146	25	3	1	11					2,030	1.06%
Family Docs	481	756	605	690	160	247	661	283	121	27	118	6	29					3,898	2.04%
Grand Total	51,989	50,275	34,282	38,831	21,159	17,359	644	11,920	1,093	4,761	610	697	498					59,986	5.14%
% of Total Hits by Custodian	20.73%	20.05%	13.67%	15.00%	8.44%	6.92%	6.49%	2.84%	1.90%	1.90%	1.05%	0.67%	0.67%	0.12%	0.12%	0.04%	0.01%	250,753	

Appendix F**Discarded Plaintiff Anchor Terms – Priority Custodians Detailed Hit Report**

This report shows the number of raw hits using Plaintiff's discarded 22 Anchor Terms and 171 Connector Terms as applied to Plaintiff's Priority Custodians.

Custodian	"Bird's Nest"	"Opt Ease"	"Right Spine"	"Vena Tech"	collected	Greenfield	K022236	K031328	K050558	K052578	K062887	K073090	K080668	K082305	K093659	K101431	K112487	K0944353	Trapease	tuip	Family Dogs	Grand Total	% Hits by Cust.		
Modra, Chad	71	8	26	105	375	175	6	5	4	6	2	5	7	2	1			1		249	344	1,174	2,566	33.74%	
Edwards, Mary	49	2		36		197	101	48											45	78	137	495	1,188	15.62%	
Lehmann, John	130	5		130	1	278	13	12	12			1								96	186	245	1,109	14.58%	
DeFord, John	10	1	37	22	106	142	6	6	6	2	10	11	4	4	3	3				34	129	314	850	11.18%	
Ring, Tim	1		2	2	8	159	2	2	2											3	55	342	576	7.57%	
Altonaga, Bill	21	4	15	16	60	91	4	2	2			11				1		1		45	83	134	490	6.44%	
Kowalczyk, Paul		1	34	3	14	14							1	2						8	21	133	231	3.04%	
Tessmer, Alex					36	14														4	46	61	161	2.12%	
Garcia, Jose			42		1	1							1									1	87	133	1.75%
Raji-Kubba, Abthal	1	1	5	3	36	23		1	1	1	1	1	1	1	1	1				14	27	10	129	1.70%	
Dolch, Gary			2	2		15								4						3	5	41	70	0.92%	
Johnson, Michelle			3	3		18														2	4	32	64	0.84%	
Bliss, Richard	6		1	4		5				1										5	6	3	31	0.41%	
Mukherjee, Avijit				1	2	2																3	6	0.08%	
Glass, Holly						1																	1	0.01%	
Total	289	24	163	327	637	1,135	132	76	27	10	14	29	15	11	5	5	2		45	541	1,044	3,074	7605		
% Hits by Term	6.38%	0.53%	3.60%	7.22%	14.06%	25.05%	2.91%	1.68%	0.60%	0.22%	0.31%	0.64%	0.33%	0.24%	0.11%	0.11%	0.04%		0.99%	11.94%	23.04%				

Appendix G**Discarded Plaintiff Anchor Terms – Original Bard Custodians Detailed Hit Report**

This report shows the number of raw hits using Plaintiff's discarded 22 Anchor Terms and 171 Connector Terms as applied to the Original Bard Custodians.

Custodian	"Bird's Nest"	"Opt Ease"	"tight spline"	"Vena Tech"	cellect	Greenfield	K02236	K031328	K050558	K052578	K062887	K073090	K080668	K082305	K094353	Trapease	tulip	Family Docs	Grand Total	% Hits by Cust.
Klocke, Stephanie				1,070		3	7			2								8	194	1,284 38.00%
Beasley, Jim	12	6	20	18	135	70		1					1	2	1		27	114	271	678 20.07%
Wong, Natalie				382		13	6					1						4	48	454 13.44%
DeFord, John	3			16	3	5	24										4	11	92	158 4.68%
Ganser, Christopher	23				15		28										27	34	1	128 3.79%
Chanduszko, Andre				59		2	5											6	26	98 2.90%
Hudson, Brian	1			45	2	3	15										2	4	18	90 2.66%
Simpson, Charlie				35			3												11	49 1.45%
Howard, James				3			1					2	3					2	29	40 1.18%
Hudnall, Janet				29		4	3				1							9	2	48 1.42%
Salzmann, Dennis				40															6	46 1.36%
Carr, Robert				23		2	7											2	10	44 1.30%
Ciavarella, David	4				4		6			1	1	1					6	14	5	42 1.24%
Estrada, Tracy				26			1												5	32 0.95%
Harmison, Heather				20															8	28 0.83%
Walcott, Cindi				7			15												6	28 0.83%
Schulz, Gin	2			9			2											1	6	20 0.59%
Nielsen, Mary							14										1		4	19 0.56%
Randall, Mike				7			8										2		17	0.50%
Baird, Bret						5	2											4	4	15 0.44%
Cherry, Joe							6												8	14 0.41%
Balutowski, Genevieve							1				5								3	9 0.27%
Brown, Brian							8												8	0.24%
DuBois, Tom	7																		7	0.21%
Conaway, John				3			2												5	0.15%
Fitzpatrick, Ed				5															5	0.15%
Dunn, Chris							3												3	0.09%
Hayes, Wendy							2												1	3 0.09%
Palermo, Pete							1												1	2 0.06%
Uelmen, Doug							1												1	2 0.06%
Weiland, John							2												2	0.06%
Barker, Elaine	1																		1	0.03%
Total	53	6	1799	42	172	243	0	1	1	9	4	4	2	1	0	69	213	760	3379	
% Hits by Term	2.02%	0.23%	68.69%	1.60%	6.57%	9.28%	0.00%	0.04%	0.04%	0.34%	0.15%	0.15%	0.08%	0.04%	0.00%	2.63%	8.13%			

EXHIBIT D



39 Broadway, 26th Floor
New York, NY 10006

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www.biaprotect.com

October 23, 2013

Phillips v. C. R. Bard, Inc., et al (3:12-cv-00344-RJ-WGC)

RESULTS OF "SAMPLING EXERCISE":

On May 22, 2013, BIA submitted its Proposed Discovery Protocol Analysis Report, which included 7 proposed search alterations designed to reduce the overall document count. On May 29, 2013, the Court ordered the parties and their ESI consultants to discuss a sampling process regarding Proposals 2 through 6.

Pursuant to the Court's Order, with respect to Proposals 2 through 6, BIA took each Proposal Set (i.e., the total number of documents that met the criteria for each Proposal and that had not yet been produced to Plaintiffs) and used the statistical sampling calculator located at <http://www.surveysystem.com/sscalc.htm> to determine the sample size for review. To obtain the relevant sample size for review, BIA input the confidence level as 95%, with a confidence level of 1 for each of the applicable Proposals. Using the relevant sample size for review for each Proposal Set, BIA input the total number of documents for each Proposal Set in the Population Field and clicked "Calculate," which provided the sample size needed for review for each Proposal Set.

Once BIA had the sample size needed for review for each Proposal Set, BIA used the "Create Random Sample" script (created by kCura, owner of Relativity review tool). The script asks for the location of the saved search (which contained the entire Proposal Set for each Proposal) and the number of documents needed for review, which BIA input with the same number that the Sample Size Calculator generated. From there, the script was run only once, and the script takes the number of documents needing to be sampled and randomly flags that number as "Yes", while flagging the rest of the population as "No". BIA then set up review sets for their review team to review all documents that were flagged as "Yes". Once completed, the results were tallied and reported back to the parties.

SAMPLE SIZES USING A CONFIDENCE LEVEL OF 95% WITH A CONFIDENCE INTERVAL OF 1



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PROPOSAL 2	Documents in Proposal Set	7,887	Documents sampled	4,331
<i>C.R. Bard's original search terms with no connector terms</i>				
Review determination	Non-responsive	837	Responsive	3,494
			Privileged	155
	Percent Responsive	80.7%		

PROPOSAL 3	Documents in Proposal Set	58,713	Documents sampled	8,254
<i>Custodians Ring and DeFord with all terms excluding failure terms</i>				
Review determination	Non-responsive	6,692	Responsive	1,562
			Privileged	116
	Percent Responsive	18.9%		



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PROPOSAL 4	Documents in Proposal Set	26,352	Documents sampled	7,039
<i>Off-label documents</i>				
Review determination	Non-responsive	5,725	Responsive	1,314
			Privileged	127
	Percent Responsive	18.7%		

PROPOSAL 5	Documents in Proposal Set	2,551	Documents sampled	2,016
<i>Competitor terms only</i>				
Review determination	Non-responsive	1,111	Responsive	905
			Privileged	216
	Percent Responsive	44.9%		

PROPOSAL 6	Documents in Proposal Set	1,003	Documents sampled	1,003
<i>Non-producing file types (logos, signature blocks, etc.)</i>				
Review determination	Non-responsive	1,003	Responsive	0
			Privileged	0
	Percent Responsive	0%		



39 Broadway, 26th Floor
New York, NY 10006

T: 212.240.2282

F: 212.240.2298

www.biaprotect.com

ALL PROPOSALS			Documents sampled	21,545
<i>Proposals 2, 3, 4, 5, and 6 combined</i>				
Review determination	Non-responsive	14,286	Responsive	7,259
			Privileged	604
	Percent Responsive	33.7%		

Appendix D:

Plaintiffs' Rule 30(b)(6) Deposition Notices:

Threshold

Opinion Leaders and Sales

Meridian and Denali

Robert W. Boatman (009619) - rwb@gknet.com
Paul L. Stoller (016773) - paul.stoller@gknet.com
Shannon L. Clark (019708) - SLC@gknet.com
GALLAGHER & KENNEDY, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
Telephone: (602) 530-8000

Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
rlopez@lopezmchugh.com
Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS
PRODUCTS LIABILITY LITIGATION

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' NOTICE OF
DEPOSITION PURSUANT TO
FEDERAL RULE OF CIVIL
PROCEDURE 30(b)(6)**

(THRESHOLD)

YOU ARE HEREBY NOTIFIED that, in accordance with Rule 30(b)(6),
Fed. R. Civ. P., Plaintiffs will depose the representative of C. R. Bard, Inc. and Bard
Peripheral Vascular, Inc. ("BARD") who is the most knowledgeable regarding the
following matters set forth in Exhibit A.

DATE/TIME OF DEPOSITION: TBD

LOCATION OF DEPOSITION: Gallagher & Kennedy, P.A.
2575 East Camelback Road, Suite 1100
Phoenix, Arizona 85016

The deposition will be taken upon oral examination before a stenographic court
reporter or some other officer duly authorized by law to take oaths and acknowledgements
in the State of Arizona. The deposition will continue day to day until completed and will
be videotaped. This deposition is being taken for the purpose of discovery, for use at trial
or both of the foregoing, or for such other purposes as permitted under the applicable rules
and governing law.

1 DATED this 28th day of September, 2016.

2 **GALLAGHER & KENNEDY, P.A.**

3
4 By: 

5 Robert W. Boatman
6 Paul L. Stoller
7 Shannon L. Clark
8 2575 East Camelback Road
9 Phoenix, Arizona 85016-9225

10 **LOPEZ McHUGH LLP**

11 Ramon Rossi Lopez (CA Bar No. 86361)
12 (admitted *pro hac vice*)
13 100 Bayview Circle, Suite 5600
14 Newport Beach, California 92660

15 *Co-Lead/Liaison Counsel for Plaintiffs*

16 **CERTIFICATE OF SERVICE**

17 I hereby certify that on September 28, 2016, a true and correct copy of the
18 foregoing was sent via U.S. Mail and/or Electronic Mail to:

19 James R. Condo
20 Snell & Wilmer LLP
21 400 East Van Buren Street, Suite 1900
22 Phoenix, Arizona 85004
23 *Attorneys for Defendants*

24 Richard B. North, Jr.
25 Nelson Mullins Riley & Scarborough LLP
26 Atlantic Station
27 201 17th Street NW, Suite 1700
28 Atlanta, Georgia 30363
Attorneys for Defendants

*Counsel for Plaintiffs will be served in accordance
with the Court's Case Management Order No. 1

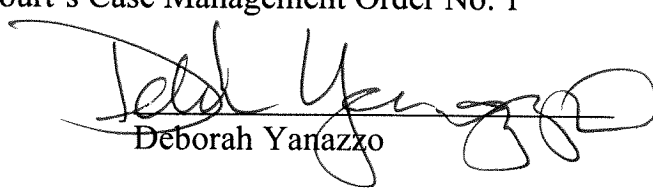

Deborah Yanazzo

EXHIBIT A

Definitions

The following definitions apply to this Notice of Deposition, including those matters set forth in Exhibit A hereto, and are deemed to be incorporated into each subject and request for documents listed below:

1. “Identify” or “identity” with respect to persons, means to give, to the extent known, the person’s full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment.

2. BARD means Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., and any of its subsidiaries, affiliates, officers, agents, attorneys, employees, representatives, or others acting on its behalf.

3. “Person” means natural person, as well as corporate and/or governmental entity.

4. “IVC Filter” means all IVC Filters manufactured or distributed by BARD or its predecessors prior to assignment or sale of such filters to BARD. Also included is any device intended to retrieve any filter or to introduce any filter into the body.

5. “Relating to,” “relate to,” “referring to,” “refer to,” “reflecting,” “reflect,” “with regard to,” “concerning,” or “concern” shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in the preparation of or concerning the preparation of the documents.

6. “Documents” as used in this Request is coextensive with the meaning of the terms “documents” and “tangible things” in FRCP 34, and shall have the broadest possible meaning and interpretation ascribed to the terms “documents” and “tangible things” under FRCP 34. Consistent with the above definition, the term document shall include, without limitation, any written, printed, typed, photostatic, photographed,

1 recorded, computer-generated, computer- stored, or otherwise maintained or reproduced
 2 communication or representation, any data compilation in any form, whether comprised of
 3 letters, words, numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses,
 4 electronic data, active files, deleted files, file fragments, or any combination thereof
 5 including, without limitation, all memoranda, notes, records, letters, envelopes, telegrams,
 6 messages, studies, analyses, contracts, agreements, projections, estimates, working papers,
 7 accounts, analytical records, reports and/or summaries of investigations, opinions or
 8 reports of consultants, opinions or reports of experts, opinions or reports of accountants,
 9 other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines,
 10 newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts,
 11 drawings, diagrams, instructions, minutes of meetings or communications of any type,
 12 including inter- and intra-office communications, questionnaires, surveys, charts, graphs,
 13 photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all other
 14 compiled data which can be obtained (translated, if necessary, through intermediary or
 15 other devices into usable forms), documents maintained on, stored in or generated on any
 16 electronic transfer or storage system, any preliminary versions, drafts or revisions of any
 17 of the foregoing, and other writings or documents of whatever description or kind, whether
 18 produced or authorized by or on behalf of you or anyone else, and shall include all non-
 19 identical copies and drafts of any of the foregoing now in the possession, custody or
 20 control of you, or the former or present directors, officers, counsel, agents, employees,
 21 partners, consultants, principals, and/or persons acting on your behalf.

22 7. "Or" and "and" will be used interchangeably.

23 **Deposition Subject Matter**

24 Pursuant to Rule 30(b)(6), BARD shall designate and produce for deposition one or
 25 more of its officers, directors, managing agents, or other persons who consent to testify on
 26 its behalf concerning the following subject matters:
 27
 28

1 **1. Recovery filter**

2 a) The filter's design thresholds for acceptable failure rates for any failure
3 mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular
4 has referred to these thresholds as rate of occurrence, expected frequency of occurrence,
5 expected malfunction rates, occurrence rates and acceptable rates of occurrence.

6 b) The basis or rationale for establishing the filter's design thresholds for
7 acceptable failure rates for any failure mode related to migration, fracture or
8 perforation/penetration.

9 c) The purpose of establishing the filter design thresholds for acceptable failure
10 rates for any failure mode related to migration, fracture or perforation/penetration.

11 d) Any and all efforts to communicate the filter's design thresholds for
12 acceptable failure rates for any failure mode related to migration, fracture or
13 perforation/penetration.to the Food and Drug Administration.

14 e) Any and all efforts to communicate the filter's design thresholds for
15 acceptable failure rates for any failure mode related to migration, fracture or
16 perforation/penetration to any physicians in the medical community (physicians not
17 employees or consultant of YOU).

18 f) Any changes made to the filter's thresholds for acceptable failure rates for
19 any failure mode related to migration, fracture or perforation/penetration after this product
20 was first sold by YOU on the market place.

21 g) The reason for any change made to the filter's thresholds for acceptable
22 failure rates for any failure mode related to migration, fracture or perforation/penetration
23 after this product was first sold by YOU on the market place.

24 h) Any and all efforts to communicate any changes YOU made to YOUR
25 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
26 perforation/penetration after this product was first sold by YOU on the market place.

i) Any and all efforts to communicate any changes YOU made to YOUR thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in the medical community (not employees or consultant of YOU).

j) What the Occurrence Rating ["O" column], by failure mode, listed in YOUR DFMEA for filter at the time of its release for sale on the marketplace.

k) How YOU established the numerical value represented by the Occurrence Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the time of its release for sale on the marketplace.

l) The purpose of the Occurrence Rating ["O" column] for each failure mode listed in YOUR DFMEAs for the filter at the time of its release for sale.

m) Any changes YOU made to the Occurrence Rating ["O" column] of any failure mode in YOUR DFMEAs for filter after its release for sale.

n) The reason for any change YOU made to the Occurrence Rating ["O" column] of any failure mode in YOUR DFMEA for the filter after this product was first sold by you on the market place.

2. G2

a) The filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular has referred to these thresholds as rate of occurrence, expected frequency of occurrence, expected malfunction rates, occurrence rates and acceptable rates of occurrence.

b) The basis or rationale for establishing the filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.

c) The purpose of establishing the filter design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.

d) Any and all efforts to communicate the filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.to the Food and Drug Administration.

1 e) Any and all efforts to communicate the filter's design thresholds for
2 acceptable failure rates for any failure mode related to migration, fracture or
3 perforation/penetration to any physicians in the medical community (physicians not
4 employees or consultant of YOU).

5 f) Any changes made to the filter's thresholds for acceptable failure rates for
6 any failure mode related to migration, fracture or perforation/penetration after this product
7 was first sold by YOU on the market place.

8 g) The reason for any change made to the filter's thresholds for acceptable
9 failure rates for any failure mode related to migration, fracture or perforation/penetration
10 after this product was first sold by YOU on the market place.

11 h) Any and all efforts to communicate any changes YOU made to YOUR
12 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
13 perforation/penetration after this product was first sold by YOU on the market place.

14 i) Any and all efforts to communicate any changes YOU made to YOUR
15 thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in
16 the medical community (not employees or consultant of YOU).

17 j) What the Occurrence Rating ["O" column], by failure mode, listed in
18 YOUR DFMEA for filter at the time of its release for sale on the marketplace.

19 k) How YOU established the numerical value represented by the Occurrence
20 Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the
21 time of its release for sale on the marketplace.

22 l) The purpose of the Occurrence Rating ["O" column] for each failure mode
23 listed in YOUR DFMEAs for the filter at the time of its release for sale.

24 m) Any changes YOU made to the Occurrence Rating ["O" column] of any
25 failure mode in YOUR DFMEAs for filter after its release for sale.

26 n) The reason for any change YOU made to the Occurrence Rating ["O"
27 column] of any failure mode in YOUR DFMEA for the filter after this product was first
28 sold by you on the market place.

1
2 **3. G2 Express**

3 a) The filter's design thresholds for acceptable failure rates for any failure
4 mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular
5 has referred to these thresholds as rate of occurrence, expected frequency of occurrence,
6 expected malfunction rates, occurrence rates and acceptable rates of occurrence.

7 b) The basis or rationale for establishing the filter's design thresholds for
8 acceptable failure rates for any failure mode related to migration, fracture or
9 perforation/penetration.

10 c) The purpose of establishing the filter design thresholds for acceptable failure
11 rates for any failure mode related to migration, fracture or perforation/penetration.

12 d) Any and all efforts to communicate the filter's design thresholds for
13 acceptable failure rates for any failure mode related to migration, fracture or
14 perforation/penetration.to the Food and Drug Administration.

15 e) Any and all efforts to communicate the filter's design thresholds for
16 acceptable failure rates for any failure mode related to migration, fracture or
17 perforation/penetration to any physicians in the medical community (physicians not
18 employees or consultant of YOU).

19 f) Any changes made to the filter's thresholds for acceptable failure rates for
20 any failure mode related to migration, fracture or perforation/penetration after this product
21 was first sold by YOU on the market place.

22 g) The reason for any change made to the filter's thresholds for acceptable
23 failure rates for any failure mode related to migration, fracture or perforation/penetration
24 after this product was first sold by YOU on the market place.

25 h) Any and all efforts to communicate any changes YOU made to YOUR
26 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
27 perforation/penetration after this product was first sold by YOU on the market place.
28

i) Any and all efforts to communicate any changes YOU made to YOUR thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in the medical community (not employees or consultant of YOU).

j) What the Occurrence Rating ["O" column], by failure mode, listed in YOUR DFMEA for filter at the time of its release for sale on the marketplace.

k) How YOU established the numerical value represented by the Occurrence Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the time of its release for sale on the marketplace.

l) The purpose of the Occurrence Rating ["O" column] for each failure mode listed in YOUR DFMEAs for the filter at the time of its release for sale.

m) Any changes YOU made to the Occurrence Rating ["O" column] of any failure mode in YOUR DFMEAs for filter after its release for sale.

n) The reason for any change YOU made to the Occurrence Rating ["O" column] of any failure mode in YOUR DFMEA for the filter after this product was first sold by you on the market place.

4. G2 X

a) The filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular has referred to these thresholds as rate of occurrence, expected frequency of occurrence, expected malfunction rates, occurrence rates and acceptable rates of occurrence.

b) The basis or rationale for establishing the filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.

c) The purpose of establishing the filter design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.

d) Any and all efforts to communicate the filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.to the Food and Drug Administration.

1 e) Any and all efforts to communicate the filter's design thresholds for
2 acceptable failure rates for any failure mode related to migration, fracture or
3 perforation/penetration to any physicians in the medical community (physicians not
4 employees or consultant of YOU).

5 f) Any changes made to the filter's thresholds for acceptable failure rates for
6 any failure mode related to migration, fracture or perforation/penetration after this product
7 was first sold by YOU on the market place.

8 g) The reason for any change made to the filter's thresholds for acceptable
9 failure rates for any failure mode related to migration, fracture or perforation/penetration
10 after this product was first sold by YOU on the market place.

11 h) Any and all efforts to communicate any changes YOU made to YOUR
12 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
13 perforation/penetration after this product was first sold by YOU on the market place.

14 i) Any and all efforts to communicate any changes YOU made to YOUR
15 thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in
16 the medical community (not employees or consultant of YOU).

17 j) What the Occurrence Rating ["O" column], by failure mode, listed in
18 YOUR DFMEA for filter at the time of its release for sale on the marketplace.

19 k) How YOU established the numerical value represented by the Occurrence
20 Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the
21 time of its release for sale on the marketplace.

22 l) The purpose of the Occurrence Rating ["O" column] for each failure mode
23 listed in YOUR DFMEAs for the filter at the time of its release for sale.

24 m) Any changes YOU made to the Occurrence Rating ["O" column] of any
25 failure mode in YOUR DFMEAs for filter after its release for sale.

26 n) The reason for any change YOU made to the Occurrence Rating ["O"
27 column] of any failure mode in YOUR DFMEA for the filter after this product was first
28 sold by you on the market place.

1 **5. Eclipse**

2 a) The filter's design thresholds for acceptable failure rates for any failure
3 mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular
4 has referred to these thresholds as rate of occurrence, expected frequency of occurrence,
5 expected malfunction rates, occurrence rates and acceptable rates of occurrence.

6 b) The basis or rationale for establishing the filter's design thresholds for
7 acceptable failure rates for any failure mode related to migration, fracture or
8 perforation/penetration.

9 c) The purpose of establishing the filter design thresholds for acceptable failure
10 rates for any failure mode related to migration, fracture or perforation/penetration.

11 d) Any and all efforts to communicate the filter's design thresholds for
12 acceptable failure rates for any failure mode related to migration, fracture or
13 perforation/penetration.to the Food and Drug Administration.

14 e) Any and all efforts to communicate the filter's design thresholds for
15 acceptable failure rates for any failure mode related to migration, fracture or
16 perforation/penetration to any physicians in the medical community (physicians not
17 employees or consultant of YOU).

18 f) Any changes made to the filter's thresholds for acceptable failure rates for
19 any failure mode related to migration, fracture or perforation/penetration after this product
20 was first sold by YOU on the market place.

21 g) The reason for any change made to the filter's thresholds for acceptable
22 failure rates for any failure mode related to migration, fracture or perforation/penetration
23 after this product was first sold by YOU on the market place.

24 h) Any and all efforts to communicate any changes YOU made to YOUR
25 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
26 perforation/penetration after this product was first sold by YOU on the market place.

i) Any and all efforts to communicate any changes YOU made to YOUR thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in the medical community (not employees or consultant of YOU).

j) What the Occurrence Rating ["O" column], by failure mode, listed in YOUR DFMEA for filter at the time of its release for sale on the marketplace.

k) How YOU established the numerical value represented by the Occurrence Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the time of its release for sale on the marketplace.

l) The purpose of the Occurrence Rating ["O" column] for each failure mode listed in YOUR DFMEAs for the filter at the time of its release for sale.

m) Any changes YOU made to the Occurrence Rating ["O" column] of any failure mode in YOUR DFMEAs for filter after its release for sale.

n) The reason for any change YOU made to the Occurrence Rating ["O" column] of any failure mode in YOUR DFMEA for the filter after this product was first sold by you on the market place.

6. Meridian

a) The filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular has referred to these thresholds as rate of occurrence, expected frequency of occurrence, expected malfunction rates, occurrence rates and acceptable rates of occurrence.

b) The basis or rationale for establishing the filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.

c) The purpose of establishing the filter design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.

d) Any and all efforts to communicate the filter's design thresholds for acceptable failure rates for any failure mode related to migration, fracture or perforation/penetration.to the Food and Drug Administration.

1 e) Any and all efforts to communicate the filter's design thresholds for
2 acceptable failure rates for any failure mode related to migration, fracture or
3 perforation/penetration to any physicians in the medical community (physicians not
4 employees or consultant of YOU).

5 f) Any changes made to the filter's thresholds for acceptable failure rates for
6 any failure mode related to migration, fracture or perforation/penetration after this product
7 was first sold by YOU on the market place.

8 g) The reason for any change made to the filter's thresholds for acceptable
9 failure rates for any failure mode related to migration, fracture or perforation/penetration
10 after this product was first sold by YOU on the market place.

11 h) Any and all efforts to communicate any changes YOU made to YOUR
12 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
13 perforation/penetration after this product was first sold by YOU on the market place.

14 i) Any and all efforts to communicate any changes YOU made to YOUR
15 thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in
16 the medical community (not employees or consultant of YOU).

17 j) What the Occurrence Rating ["O" column], by failure mode, listed in
18 YOUR DFMEA for filter at the time of its release for sale on the marketplace.

19 k) How YOU established the numerical value represented by the Occurrence
20 Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the
21 time of its release for sale on the marketplace.

22 l) The purpose of the Occurrence Rating ["O" column] for each failure mode
23 listed in YOUR DFMEAs for the filter at the time of its release for sale.

24 m) Any changes YOU made to the Occurrence Rating ["O" column] of any
25 failure mode in YOUR DFMEAs for filter after its release for sale.

26 n) The reason for any change YOU made to the Occurrence Rating ["O"
27 column] of any failure mode in YOUR DFMEA for the filter after this product was first
28 sold by you on the market place.

1
2 **7. Denali**

3 a) The filter's design thresholds for acceptable failure rates for any failure
4 mode related to migration, fracture or perforation/penetration. Bard Peripheral Vascular
5 has referred to these thresholds as rate of occurrence, expected frequency of occurrence,
6 expected malfunction rates, occurrence rates and acceptable rates of occurrence.

7 b) The basis or rationale for establishing the filter's design thresholds for
8 acceptable failure rates for any failure mode related to migration, fracture or
9 perforation/penetration.

10 c) The purpose of establishing the filter design thresholds for acceptable failure
11 rates for any failure mode related to migration, fracture or perforation/penetration.

12 d) Any and all efforts to communicate the filter's design thresholds for
13 acceptable failure rates for any failure mode related to migration, fracture or
14 perforation/penetration.to the Food and Drug Administration.

15 e) Any and all efforts to communicate the filter's design thresholds for
16 acceptable failure rates for any failure mode related to migration, fracture or
17 perforation/penetration to any physicians in the medical community (physicians not
18 employees or consultant of YOU).

19 f) Any changes made to the filter's thresholds for acceptable failure rates for
20 any failure mode related to migration, fracture or perforation/penetration after this product
21 was first sold by YOU on the market place.

22 g) The reason for any change made to the filter's thresholds for acceptable
23 failure rates for any failure mode related to migration, fracture or perforation/penetration
24 after this product was first sold by YOU on the market place.

25 h) Any and all efforts to communicate any changes YOU made to YOUR
26 thresholds for acceptable failure rates for any failure mode related to migration, fracture or
27 perforation/penetration after this product was first sold by YOU on the market place.
28

1 i) Any and all efforts to communicate any changes YOU made to YOUR
2 thresholds of failure rates, by failure mode, of the (insert filter name) to the physicians in
3 the medical community (not employees or consultant of YOU).

4 j) What the Occurrence Rating ["O" column], by failure mode, listed in
5 YOUR DFMEA for filter at the time of its release for sale on the marketplace.

6 k) How YOU established the numerical value represented by the Occurrence
7 Rating ["O" column] for each failure mode listed in YOUR DFMEA for the filter at the
8 time of its release for sale on the marketplace.

9 l) The purpose of the Occurrence Rating ["O" column] for each failure mode
10 listed in YOUR DFMEAs for the filter at the time of its release for sale.

11 m) Any changes YOU made to the Occurrence Rating ["O" column] of any
12 failure mode in YOUR DFMEAs for filter after its release for sale.

13 n) The reason for any change YOU made to the Occurrence Rating ["O"
14 column] of any failure mode in YOUR DFMEA for the filter after this product was first
15 sold by you on the market place.

Robert W. Boatman (009619) – rwb@gknet.com
 Paul L. Stoller (016773) – paul.stoller@gknet.com
 Shannon L. Clark (019708) – SLC@gknet.com
GALLAGHER & KENNEDY, P.A.
 2575 East Camelback Road
 Phoenix, Arizona 85016-9225
 Telephone: (602) 530-8000

Ramon Rossi Lopez (CA Bar No. 86361)
 (admitted *pro hac vice*)
LOPEZ McHUGH LLP
 100 Bayview Circle, Suite 5600
 Newport Beach, California 92660
 rlopez@lopezmchugh.com

Stuart L. Goldenberg (MN Bard No. 158719)
 (admitted *pro hac vice*)
GOLDENBERGLAW, PLLC
 800 LaSalle Avenue, Suite 2150
 Minneapolis, MN 55402
 Telephone: (612) 333-4662
 slgoldenberg@goldenberglaw.com
 Co-Lead/Liaison Counsel/Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
 DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS
 PRODUCTS LIABILITY LITIGATION

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' AMENDED NOTICE
 OF DEPOSITION PURSUANT TO
 FEDERAL RULE OF CIVIL
 PROCEDURE 30(b)(6)**

(OPINION LEADERS AND SALES)

YOU ARE HEREBY NOTIFIED that, in accordance with Rule 30(b)(6), Fed. R. Civ. P., Plaintiffs will depose the representative of C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. ("BARD") who is the most knowledgeable regarding the following matters set forth in exhibit A.

DATE/TIME OF DEPOSITION: TBD


LOCATION OF DEPOSITION: Gallagher & Kennedy, P.A.
 2575 East Camelback Road
 Phoenix, Arizona 85016

The deposition will be taken upon oral examination before a stenographic court reporter or some other officer duly authorized by law to take oaths and acknowledgements

1 in the State of Arizona. The deposition will continue day to day until completed and will
2 be videotaped. This deposition is being taken for the purpose of discovery, for use at trial
3 or both of the foregoing, or for such other purposes as permitted under the applicable rules
4 and governing law.

5
6 DATED this 28th day of September, 2016.

7 **GALLAGHER & KENNEDY, P.A.**

8
9 By: 
10 Robert W. Boatman
11 Paul L. Stoller
12 Shannon L. Clark
13 2575 East Camelback Road
14 Phoenix, Arizona 85016-9225

15 **LOPEZ McHUGH LLP**

16 Ramon Rossi Lopez (CA Bar No. 86361)
17 (admitted *pro hac vice*)
18 100 Bayview Circle, Suite 5600
19 Newport Beach, California 92660

20 **GOLDENBERGLAW, PLLC**

21 Stuart L. Goldenberg (MN Bar No.)
22 (admitted *pro hac vice*)
23 800 LaSalle Avenue, Suite 2150
24 Minneapolis, Minnesota 55402

25 *Co-Lead/Liaison Counsel/Counsel for Plaintiffs*

26 **CERTIFICATE OF SERVICE**

27 I hereby certify that on September 28, 2016 a true and correct copy of the
28 foregoing was sent via U.S. Mail and/or Electronic Mail to:

James R. Condo
Snell & Wilmer LLP
400 East Van Buren Street, Suite 1900
Phoenix, Arizona 85004
Attorneys for Defendants

Richard B. North, Jr.
Nelson Mullins Riley & Scarborough LLP
Atlantic Station

201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Attorneys for Defendants

*Counsel for Plaintiffs will be served in
accordance with the Court's Case Management
Order No. 1

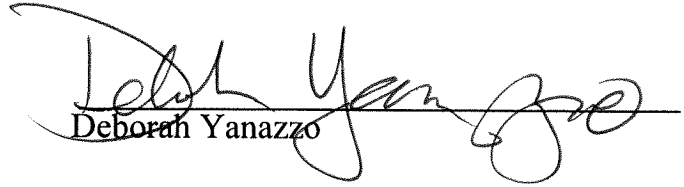

Deborah Yanazzo

EXHIBIT A

Definitions

The following definitions apply to this Notice of Deposition, including those matters set forth in Exhibit A hereto, and are deemed to be incorporated into each subject and request for documents listed below:

1. “Identify” or “identity” with response to persons, means to give, to the extent known, the person’s full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment.

2. BARD means Defendants C. R. BARD, INC. and BARD PEROPHERAL VASCULAR, INC., and any of its subsidiaries, affiliates, officers, agents, attorneys, employees, representatives, or others acting on its behalf.

3. “Person” means natural person, as well as corporate and/or governmental entity.

4. “RELEVANT PRODUCTS” or “IVC Filter” means all IVC Filters manufactured or distributed by BARD or its predecessors prior to assignment or sale of such filters to BARD. Also included is any device intended to retrieve any filter or to introduce any filter into the body.

5. “Relating to,” “relate to,” “referring to,” “refer to,” “reflecting,” “reflect,” “with regard to,” “concerning,” or “concern” shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with ,relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in the preparation of or concerning the preparation of the documents.

6. “Documents” as used in this Request is coextensive with the meaning of the terms “documents” and “tangible things” in FRCP 34, and shall have the broadest possible meaning and interpretation ascribed to the terms “documents” and “tangible things” under FRCP 34. Consistent with the above definition, the term document shall include, without

1 limitation, any written, printed, typed, photostatic, photographed, recorded, computer-
2 generated, computer-stored, or otherwise maintained or reproduced communication or
3 representation, any data compilation in any form, whether comprised of letters, words,
4 numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data,
5 active files, deleted files, file fragments, or any combination thereof including, without
6 limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies,
7 analyses, contracts, agreements, projections, estimates, workings papers, accounts,
8 analytical records, reports and/or summaries of investigations, opinions or reports of
9 consultants, opinions or reports of experts, opinions or reports of accountants, other
10 reports, trade letters, press releases, comparisons, books, diaries, articles, magazines,
11 newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts,
12 drawings, diagrams, instructions, minutes of meetings or communications of any type,
13 including inter- and intra-office communications, questionnaires, surveys, charts, graphs,
14 photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all other
15 compiled data which can be obtained (translated, if necessary, through intermediary or
16 other devices into usable forms), documents maintained on, stored in or generated on any
17 electronic transfer or storage system, any preliminary versions, drafts or revisions of any
18 of the foregoing, and other writings or documents of whatever description or kind,
19 whether produced or authorized by or on behalf of you or anyone else, and shall include
20 all non-identical copies and drafts of any of the foregoing now in the possession, custody
21 or control of you, or the former or present directors, officers, counsel, agents, employees,
22 partners, consultants, principals, and/or persons acting on your behalf.

23 7. “KOL” or “KOLs” refers to any key opinion leader, thought leader,
24 consultant, physician,, clinic or hospital that was part of BARD’s speaker program or
25 faculty, or a clinical investigator for BARD, or with whom BARD had a consulting
26 relationship or any other financial relationship with respect to research, publishing,
27 speaking, or advocacy efforts, whatsoever, at any time with respect to THE RELEVANT
28 PRODUCTS as defined above.

8. IFU's refer to instructions for use for the RELEVANT PRODUCTS.

9. "Or" and "and" will be used interchangeably.

Deposition Subject Matter

Pursuant to Rule 30(b)(6), BARD shall designate and produce for deposition one or more of its officers, directors, managing agents, or other persons who consent to testify on its behalf concerning the following subject matters:

1. BARD's corporate sales strategy on the RELEVANT PRODUCTS, including, but not limited to, business plans, communications and goals, medical communications plans, KOL plans, compliance plans, including involvement of KOLs and other third parties.

2. Any and all sales or marketing data collected on use of the RELEVANT PRODUCTS in a manner that is contrary to the IFUs.

3. BARD's procedures and practices regarding employment, training, and supervision of BARD sales and marketing personnel (whether employee or independent contractor) responsible for selling, marketing, promoting, and/or distributing the RELEVANT PRODUCTS to KOLs.

4. Any changes to BARD's sales and marketing goals regarding the sale, advertising, promotion, or marketing of the RELEVANT PRODUCTS or changes to relationships with KOLs resulting from adverse events or complications occurring with the RELEVANT PRODUCTS.

5. BARD's accounting systems and protocols RELATING TO sales of the RELEVANT PRODUCTS to KOLs, as well as the compensation of persons involved in the sale, distribution, and marketing of the RELEVANT PRODUCTS, including information relating to any salary, commission, incentive, bonus, sales target, sales quota, or other payment or reimbursement structures.

6. The nature and contents of any training or policies provided to BARD employees, independent contractors, and distributors whose duties included the sale, promotion, and/or distribution of the RELEVANT PRODUCTS to KOLs, including the nature and

1 contents of any information and/or instructions about the RELEVANT PRODUCTS
2 provided to the individuals whose duties included the sale, marketing, promotion, and/or
3 distribution of the RELEVANT PRODUCTS.

4 7. BARD's relationships with its KOLs relating to the implantation of a BARD IVC
5 Filter before an orthopedic surgery, bariatric surgery, cardiovascular surgery, or any other
6 type of surgical procedure(s) or in any situation that is contrary to the IFUs. These
7 relationships include but are not limited to, KOL faculty and "VIP" meetings or events,
8 Visiting Surgeon Programs ("VSPs"), sponsored programs, continuing medical education
9 courses, training, speaking engagements, medical seminars, quotas, work on products, the
10 nature of any incentives (cash or non-cash), bonus programs, travel, hotels, funding of
11 grants, consulting agreements, royalty agreements, assistance with patents, or any other
12 gifts, payments, or transfers of funds, goods, or services to KOLs.

13 8. BARD's identification, recruitment, development, and maintenance of
14 relationships with its KOLs on the RELEVANT PRODUCTS for use regarding
15 orthopedic, bariatric, cardiovascular, other surgical procedure(s) or in any situation that is
16 contrary to the IFUs.

17 9. BARD's use of or involvement or relationship with M.E.R.I.

18 10. COMMUNICATIONS between BARD and its KOLs RELATING TO studies,
19 medical literature, and medical journal articles CONCERNING the RELEVANT
20 PRODUCTS and prophylactic placement of the RELEVANT PRODUCTS for orthopedic,
21 bariatric, cardiovascular, or other surgical procedure(s) or in any situation that is contrary
22 to the IFUs.

23 11. BARD's actions RELATING TO the development, drafting, editing, researching,
24 and writing of studies, medical literature, and medical journal articles concerning the
25 RELEVANT PRODUCTS and orthopedic, bariatric, cardiovascular, or other surgical
26 procedure(s) or in any situation that is contrary to the IFUs.

27 12. BARD's testing or trials RELATING TO prophylactic placement of the
28 RELEVANT PRODUCTS or in any situation that is contrary to the IFUs.

1 13. Any employees of BARD who were warned, disciplined or fired for promoting or selling
2 the RELEVANT PRODUCTS in any situation that is contrary to the IFUs. This should include,
3 but not be limited to, the employee name, position, year, supervisor and reason for such warning,
4 discipline or firing.

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Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
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Newport Beach, California 92660
rlopez@lopezmchugh.com

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS
PRODUCTS LIABILITY LITIGATION

MD No. 02641

**PLAINTIFFS' NOTICE OF
DEPOSITION PURSUANT TO
FEDERAL RULE OF CIVIL
PROCEDURE 30(b)(6)**

(MERIDIAN® AND DENALI®)

YOU ARE HEREBY NOTIFIED that, in accordance with Rule 30(b)(6), Fed. R. Civ. P., Plaintiff will depose the representative of C R Bard Incorporated and Bard Peripheral Vascular Incorporated ("BARD") who is the most knowledgeable regarding the following matters set forth in Exhibit A.

DATE/TIME OF DEPOSITION: TBD

LOCATION OF DEPOSITION: Gallagher & Kennedy, P.A.
2575 East Camelback Road, Suite 1100
Phoenix, Arizona 85016

The deposition will be taken upon oral examination before a stenographic court reporter or some other officer duly authorized by law to take oaths and acknowledgements in the State of Arizona. The deposition will continue day to day until completed and will be videotaped. This deposition is being taken for the purpose of discovery, for use at trial

1 or both of the foregoing, or for such other purposes as permitted under the applicable rules
2 and governing law.

3 DATED this 28th day of September 2016.

4 **GALLAGHER & KENNEDY, P.A.**

5
6 By: 

7 Robert W. Boatman
8 Paul L. Stoller
9 Shannon L. Clark
2575 East Camelback Road
Phoenix, Arizona 85016-9225

10 **LOPEZ McHUGH LLP**

11 Ramon Rossi Lopez (CA Bar No. 86361)
12 (admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

13 *Co-Lead/Liaison Counsel for Plaintiffs*

14 **CERTIFICATE OF SERVICE**

15 I hereby certify that on September 28, 2016 a true and correct copy of the
16 foregoing was sent via U.S. Mail and/or Electronic Mail to:

17 James R. Condo
18 Snell & Wilmer LLP
19 One Arizona Center
400 East Van Buren Street
Suite 1900
Phoenix, Arizona 85004
Attorneys for Defendants

21 Richard B. North, Jr.
22 Nelson Mullins Riley & Scarborough LLP
Atlantic Station
23 201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
24 *Attorneys for Defendants*

25 *Counsel for Plaintiffs will be served in accordance
26 with the Court's Case Management Order No. 1

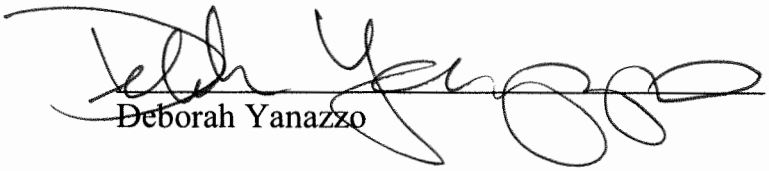
27 
28 Deborah Yanazzo

EXHIBIT A

Definitions

The following definitions apply to this Notice of Deposition, including those matters set forth in Exhibit A hereto, and are deemed to be incorporated into each subject and request for documents listed below:

1. BARD means defendants C.R. BARD INC. and BARD PERIPHERAL VASCULAR. INC., and any of its subsidiaries, affiliates, officers, agents, attorneys, employees, representatives, or others acting on its behalf.

2. Meridian means Bard's Meridian® inferior vena cava filter device, the device delivery system (both jugular and femoral) and any non-final derivation of the device.

3. Denali means Bard's Denali® inferior vena cava filter device, the device delivery system (both jugular and femoral) and any non-final derivation of the device.

4. "FDA" means the federal Food and Drug Administration.

5. "Identify" or "identity" with respect to persons, means to give, to the extent known, the person's full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment.

6. When not specifically identified otherwise, "IVC Filter(s)" is used to refer to, as broadly applicable as possible whether in the singular or plural, a Bard inferior vena cava (IVC) filter, including the Simon Nitinol Filter, Recovery Filter, G2, G2 Express, G2x, Eclipse, Meridian, Denali, and any non-final derivation of these IVC filters.

7. "Person" means natural person, as well as corporate and/or governmental entity.

8. "Relating to," "relate to," "referring to," "refer to," "reflecting," "reflect," "with regard to," "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described

1 in that paragraph of these demands, including documents attached to or used in the
2 preparation of or concerning the preparation of the documents.

3 9. As used herein, the term “Document” or “Documents” mean all written,
4 recorded, and graphic and electronically stored matter of every type and description
5 encompassed by Fed. R. Civ. P. 34(a)(1), including, but not limited to, writings, graphs,
6 charts, photographs, sound recordings, images, drawings, notes, contracts, agreements,
7 correspondence, letters, memoranda, appointment books, calendars, all forms of
8 communication (including physical documents, e-mail, instant messaging, texts, tweets,
9 social-media postings and communications), and all electronically stored information in
10 any medium from which information can be obtained either directly or, if necessary, after
11 translation by the responding party into a reasonably usable form.

12 10. “Or” and “and” will be used interchangeably.

13 **Deposition Subject Matter**

14 Pursuant to Rule 30(b)(6), BARD shall designate and produce for deposition one or
15 more of its officers, directors, managing agents, or other persons who consent to testify on
16 its behalf concerning the following subject matters:

17 1. The identity of BARD’s corporate officers and other employees (including
18 but not limited to their titles, duties, and dates of such responsibility) who were
19 responsible for the concept, designing, developing, validating, testing, labeling, marketing,
20 promoting and selling of the Meridian and Denali.

21 2. The concept, basis, reasoning, rationale, “user need(s)”, “user want(s)”,
22 “user preference(s)”, and/or necessity for BARD’s design, development and sale of the
23 Meridian and Denali.

24 3. Prelaunch Concept and design field surveys, questionnaires, and polling
25 relative to Meridian and Denali.

26 4. The date upon which the Meridian concept was first initiated by BARD.

27 5. The date upon which the Denali concept was first initiated by BARD.

28 6. Prelaunch projected sales, value propositions, cannibalization estimates, and

1 estimated market share of Meridian and Denali.

2 7. Launch plans for Meridian and Denali.

3 8. The design and development history of the Meridian and the Denali.

4 9. Feasibility test report history of the Meridian and Denali.

5 10. BARD's standards or requirements relative to improvements in the safety,
6 efficacy or retrievability of the Meridian and Denali.

7 11. Outside (e.g. physician, industry, society, competitor) standards or
8 requirements relative to the safety, efficacy or retrievability of the Meridian and Denali.

9 12. All testing (bench, animal, clinical, etc.) undertaking by BARD or on
10 BARD's behalf relative to the design, development, manufacture, marketing or sale of the
11 Meridian and Denali.

12 13. Data, studies, literature, guidelines (society, regulatory, etc.), or the like
13 (both BARD internal and external) considered by BARD specific to the concept, design,
14 feasibility, or development of the Meridian and Denali.

15 14. Failure mode analysis, including all failure mode and effects analysis
16 (process, design, etc.) relative to the Meridian and Denali.

17 15. Risk Benefit Analysis for Meridian and Denali.

18 16. All experts or consultants retained or consulted in the design, development,
19 validation, testing, labeling, marketing, promotion and sale of the Meridian and Denali.

20 17. The regulatory history of the Meridian and Denali.

21 18. The labeling history, including Instructions for Use, of the Meridian and
22 Denali.

23 19. FDA communications from and to BARD relative to the Meridian and
24 Denali.

25 20. The date Meridian was first made available for sale by BARD.

26 21. The date Denali was first made available for sale by BARD.

27 22. All studies or trials conducted or contemplated by BARD relative to the
28 Meridian and Denali.

- 1 23. Marketing, promotional and sales materials relative to Meridian and Denali.
- 2 24. Post Market Manufacturing Assessment of Meridian and Denali
- 3 25. Post Market Design Review Marketing Summary of Meridian and Denali.
- 4 26. Post Market Complaint Risk Assessment of Meridian and Denali.
- 5 27. Post Market Regulatory and Clinical Assessment of Meridian and Denali.
- 6 28. Post market customer/physician/patient surveys or feedback relative to
- 7 Meridian and Denali.
- 8 29. BARD comparisons of Meridian vs. previous BARD IVC Filters
- 9 30. BARD comparisons of Denali vs. previous BARD IVC Filters.
- 10 31. Total sales of Meridian in terms of units and U.S. Dollars.
- 11 32. Sales of Denali to date (last reported quarter) in terms of units and U.S.
- 12 Dollars.
- 13 33. Projected sales of Denali (as of last reported quarter).
- 14 34. Cannibalization of Denali relative to Eclipse and Meridian.
- 15 35. Phase out of Eclipse and Meridian relative to Denali.
- 16 36. Production hold of Meridian.
- 17 37. FDA facility inspections relative to Meridian and Denali.
- 18 38. BARD's receipt, tracking and trending of adverse events, failures,
- 19 complaints, device associated complications.
- 20 39. Complaints relative to Denali deployment or advancement.
- 21 40. BARD response to complaints relative to Denali deployment or
- 22 advancement.
- 23 41. BARD's "interim analysis" of physician Clinical Experience.
- 24 42. Post market publications or abstracts relative to Meridian and Denali.
- 25 43. Post market promotional, sales and marketing of the Meridian and Denali.
- 26 44. Fault tree, root cause, or corrective and preventative actions relative to
- 27 Meridian and Denali.
- 28